

# THE VACCINE ALLIANCE RISK & ASSURANCE REPORT 2018

Doc 06a - Annex A





## Risk & Assurance Report 2018

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## 1. Introduction

### 1.1. Purpose of this report

The future is uncertain and the environment the Alliance operates in is complex and constantly changing. With an ambitious mission in some of the world's poorest and most fragile countries, the Alliance is naturally exposed to a wide range of risks, some of which are taken consciously to achieve impact. Much like prevention of the risk of disease by vaccination is better than cure, everybody in the Alliance is expected to proactively identify and manage potential risks to Gavi's mission before they may materialise. A strong culture of risk-awareness and systematic risk management helps the Alliance to better anticipate what might happen, manage expectations, reduce vulnerabilities and make the most of opportunities for impact.

This is the third year the Alliance prepares its annual Risk & Assurance Report which discusses the most critical risks that could potentially impact the ability of the Alliance to achieve its mission and strategic goals. The report provides an update on risk management across the Alliance, an analysis of macro-trends affecting Gavi's risk profile, an overview of key changes in top risks compared to last year, and an overview of how current levels of risk compare to Gavi's risk appetite (i.e. the willingness to accept being exposed). Detailed information including analysis of each top risk and corresponding mitigation plans is included in the annexes. Where applicable, links are made with findings from audits, evaluations and other reviews where these provided assurance on the effectiveness of current mitigation measures and / or identified risks.

This year's report shows that Gavi's overall risk profile has remained relatively stable with all 15 top risks from last year still included and two additional top risks. One new risk (Polio transition) was previously unranked pending assessment and is now included as a high risk. The other new risk (IT disruption) has been elevated from a medium risk (previously named Cyber-attack) to a top risk and separated from the broader Secretariat disruption risk. The levels of some individual risks have evolved and the understanding of existing risks further enhanced based on work throughout the year by risk owners and colleagues across the Alliance and reviews in the Secretariat's Risk Committee. The report also highlights four risks outside risk appetite (up from three last year, now including Frequent or unplanned campaigns), continuing to require intensive mitigation efforts.

We continue to integrate discussions on strategy, risk and performance, allowing a coherent view of progress, current challenges and potential risks to future performance. This is reflected in the strategy update paper where links are made to top risks described in more detail in this report, and other papers include a risk lens where relevant. Risk will remain a stand-alone item at each year-end Board meeting to allow for a portfolio discussion of top risks based on this report, however when appropriate we will also use these for a deep-dive on a particular risk topic that requires Board guidance. This year there will be a discussion on approaches to fiduciary risk management in Gavi's cash grants.

### 1.2. Progress made on Alliance-wide risk management

Last year's Risk & Assurance Report described that the Secretariat had effectively implemented a comprehensive risk management and assurance approach, with new staff, processes and tools in place and enhanced risk awareness in the Secretariat and at Board level. However, it also identified scope to further refine the model, tools, and culture across the Secretariat, noted some signs of increasing risk aversion, as well as a need to more broadly disseminate Board-level discussions on top risks. It also pointed out the essential role of partners in monitoring and managing programmatic risks in country and that their roles and responsibilities in this area needed to be further clarified and operationalised. Since then, the following actions have been initiated.

**Instilling a risk-aware culture** – The Risk function launched a comprehensive intranet site explaining the Alliance’s risk philosophy and approach (including the notion of risk appetite to address signs of risk aversion), and providing easy access to all top risk assessments and corresponding Risk Committee presentations and minutes. It also includes an engaging section for staff to learn about risk management basics. The launch was announced during an all-staff presentation on risk and more in-depth brown-bag lunch sessions have been held, both in Geneva and Washington DC. New staff as well as new Board members and donors have been given introductory on-boarding presentations on the Alliance’s risk approach. Furthermore, at the last June Board meeting a pre-Board briefing on risk management has been organised. In collaboration with Gavi’s Internal Audit team, workshops have been held with the Secretariat’s Senior Management on risk management and internal control and the roles and responsibilities of management within Gavi’s three lines of defence model (see Annex I).

**Active management of top risks** – The Secretariat Risk Committee continues to systematically review all Alliance-wide top risks as approved by the Board. Each top risk is allocated to a risk owner who is responsible for ongoing monitoring and coordination of further risk analysis and mitigation and to present this to the Risk Committee (chaired by the CEO with senior leadership from across the organisation). As reflected in the Alliance KPI on risk management, to date nearly all top risks and some medium risks have been presented and discussed in-depth, including the new risk of polio transition. The Risk Committee has a regular cycle of review for each risk, with the conversations progressively moving from a focus on understanding and quantifying the risk towards discussing how to enhance mitigation, especially for risks outside appetite. Meetings are consistently minuted with clear action items laid out. A tracker has been introduced for all risk owners feeding into a dashboard for the Risk Committee to monitor any changes in exposure and progress in implementing agreed actions. The Risk function furthermore ensures that key actions to monitor and manage risks as agreed in Risk Committee meetings are included in each team’s priorities set at the start of the year, thereby mainstreaming risk management actions into the Secretariat’s regular objective-setting, budgeting and performance management process, instead of managing this as a separate stand-alone activity.

**Embedding risk management** – the Risk function has started a number of initiatives to ensure risk management capabilities are not just stand-alone activities for reporting or compliance purposes, but used actively and systematically in daily operations to inform planning and decision-making and the focus of support and oversight during grant management. This includes both structural measures such as adding risk components to existing grant management processes and tools, as well as softer measures such as supporting the business in their risk management capabilities. The Joint Appraisal template now includes a dedicated risk section for in-country stakeholders to not only appraise current performance but also identify potential risks going forward that require to be addressed proactively as part of a country’s new workplan and partners’ technical assistance. The new Country Metrics tool brings together all relevant country information to track both current performance and future risks across the different areas of grant management. Furthermore, as already referred to above, we have further integrated risk into the Secretariat’s regular performance management process, both to ensure key risk mitigation measures are tracked as part of the regular performance management process, and to inform target-setting discussions by flagging potential risks to achieving them upfront. Management discussions now integrate performance, risk and budget information to ensure these all tie together and inform each other.

**Engaging partners on risk** – The Risk function has started and planned a number of initiatives to more closely and systematically engage partners on risk. The PEF functions (core functions expected of partners at country level) now include activities to monitor and mitigate known high risk areas. Partners are required to report on their current performance against these PEF functions, and have now also been reporting new risks they see emerging in relevant programmatic areas. Furthermore an on-boarding pack has been prepared for all new Alliance staff (including partners) and this includes an introduction to the Alliance’s risk approach and top risks. We have also started to invite partner counterparts to discussions on risk such as in the Secretariat Risk

Committee. For example, the Risk Committee meeting discussing the polio transition risk was attended by the relevant technical representative of WHO.

Lastly, the Risk function is increasingly being asked by donors and peer organisations to share approaches and experiences on risk management. For example, the Global Fund has consulted Gavi on its risk appetite approach, the Global Partnership for Education has included Gavi's risk approach in its benchmarking study, and Gavi's risk appetite statement is used as an example in a risk workshop at WHO. Gavi's Risk function is regularly liaising with risk functions from other international and global health organisations, directly as well as through local risk managers networking groups.

## 2. Alliance-wide risk exposure

### 2.1. Macro trends affecting Gavi's risk profile

The Alliance operates in a volatile global environment and is exposed to continuously changing exogenous factors which could affect Gavi's risk profile. The Secretariat reviews various independent reports<sup>1</sup> on global trends and risks identified in other organisations, to evaluate to what extent these factors could represent important drivers of risk to the Gavi mission and strategic objectives. Where applicable, the trends and developments summarised below have been captured as risk factors for Gavi's top risks.

Global growth has eased but remains robust, although the possibility of financial market stress, escalating trade protectionism and heightened geopolitical tensions continue to cloud the outlook. Ten years after the financial crisis global debt has surged and interest rates are still historically low – leaving the global economy dangerously vulnerable to shocks. Increasing interest rates and dollar appreciation could trigger a debt crisis in some Gavi countries, especially in commodity exporting economies with commodity demand growth from major emerging markets expected to slow down. The economic uncertainty also continues to heighten donor funding risk, especially as Gavi comes closer to replenishment, and may equally pose risks to United Nations partners' funding. Furthermore, the planned exit of the UK from the European Union in March 2019 will likely be disruptive to global markets and supply chains, especially in a “no-deal” scenario. However, from Gavi's current assessment this would not have a significant impact on Gavi given its vaccines are not produced in the UK. Recent elections in key donor countries are reminders of continued anti-establishment, anti-globalisation and anti-immigrant sentiment in many countries. This is also reflected in growing anti-aid and anti-vaccine voices, reinforced by social media bots and trolls stoking divisions by creating fake online debate about vaccine safety. This can potentially have serious effects on both public demand and political commitment for vaccines.

Geopolitical tensions have further intensified, and especially the Middle-East remains unstable following renewed sanctions on Iran and ongoing wars in Yemen and Syria, which now also became Gavi-eligible. While state-based armed conflict decreased last year, non-state conflict has increased and security conditions remain precarious in various Gavi-supported countries in Sub-Saharan Africa with the potential to disrupt immunisation programmes. Disruptions are furthermore possible from an increase in frequency and impact of natural disasters and infectious disease outbreaks due to climate change, globalisation and urbanisation – this year saw a succession of heatwaves over the summer and the resurgence of Ebola. Both natural disasters and conflict are increasing population displacement and migration, which is a growing challenge. Also increasing population growth in Africa may create a risk that this will outpace improvements in capacity to deliver services.

Lastly, the risk of major cyber-attacks keeps rising globally. Cyber breaches recorded by businesses have almost doubled in five years, and financial costs increase year-on-year by 27.4%. Beyond financial impact, there is a growing trend of using cyber-attacks to target critical infrastructure and strategic industrial sectors, which may also impact Gavi given its complex global operations across many countries.

<sup>1</sup> Amongst others World Economic Forum Global Risks Report 2018; Eurasia Group Top Risks 2018; FEMA National Preparedness Report 2017; World Bank Global Economic Prospects 2018; Uppsala Conflict Data Program

## 2.2. Changes to the Alliance top risks in 2018

This is the third year this report has been prepared. Last year's report<sup>2</sup> prioritised 15 top risks. This year's analysis showed that the Alliance's overall risk profile has remained relatively stable with all 15 top risks from last year still included and two additional top risks included. The level of some individual risks has evolved as illustrated by the arrows next to each top risk below, and the understanding of existing risks further enhanced (see Annex IV for detailed information including analysis of each top risk and corresponding mitigation plans).

The 4 top risks rated as **very high** are:

- a) **Country management capacity**  
Many countries (continue to) have insufficient EPI capacity and capabilities to manage immunisation programmes to achieve sustainable coverage & equity
- b) **Data quality ▼**  
Continued poor availability, quality and use of immunisation data
- c) **Ability to reach the under-immunised ▼**  
The Alliance is unable to achieve equitable coverage improvements by extending immunisation services to communities previously unreached
- d) **Sustainable transition**  
Some countries fail to sustain progress of their immunisation programmes after transition

The 13 top risks rated as **high** are:

- e) **Insufficient demand**  
Significant drop or insufficient increase in vaccine demand due to hesitancy and prioritisation
- f) **Outbreaks disrupt immunisation**  
Sizeable outbreaks of infectious disease disrupt programmes in many Gavi-supported countries
- g) **Misuse by countries**  
Deliberate misuse of Gavi support in many Gavi-supported countries
- h) **Donor support**  
Reduction in donor support
- i) **Polio transition NEW**  
Loss of immunisation-critical public health capacity in Gavi countries due to the winding-down of polio eradication operations
- j) **IT disruption NEW**  
Critical information systems or data significantly compromised by cyber-attack or technology failure
- k) **Strategic relevance**  
Gavi becomes less relevant to global development priorities
- l) **Frequent or unplanned campaigns ▲**  
Frequent or unplanned mass vaccination campaigns undermine capacity of governments to manage routine health and immunisation services
- m) **Partner capacity ▼**  
Sum of comparative advantages of Alliance partners is inadequate to effectively deliver required technical support to countries
- n) **Global supply shortages**  
Shortages in the global vaccine supply
- o) **HSIS value for money**  
HSIS investments do not materially improve programmatic outcomes
- p) **Forecasting variability**  
Gavi forecasting variability driving inappropriate decision-making
- q) **Secretariat disruption ▼**  
Significant disruption of Secretariat operations

<sup>2</sup> See for the 2017 Risk & Assurance Report: <https://www.gavi.org/about/governance/gavi-board/minutes/2017/29-nov/minutes/06---risk-and-assurance-report---annex-a/>

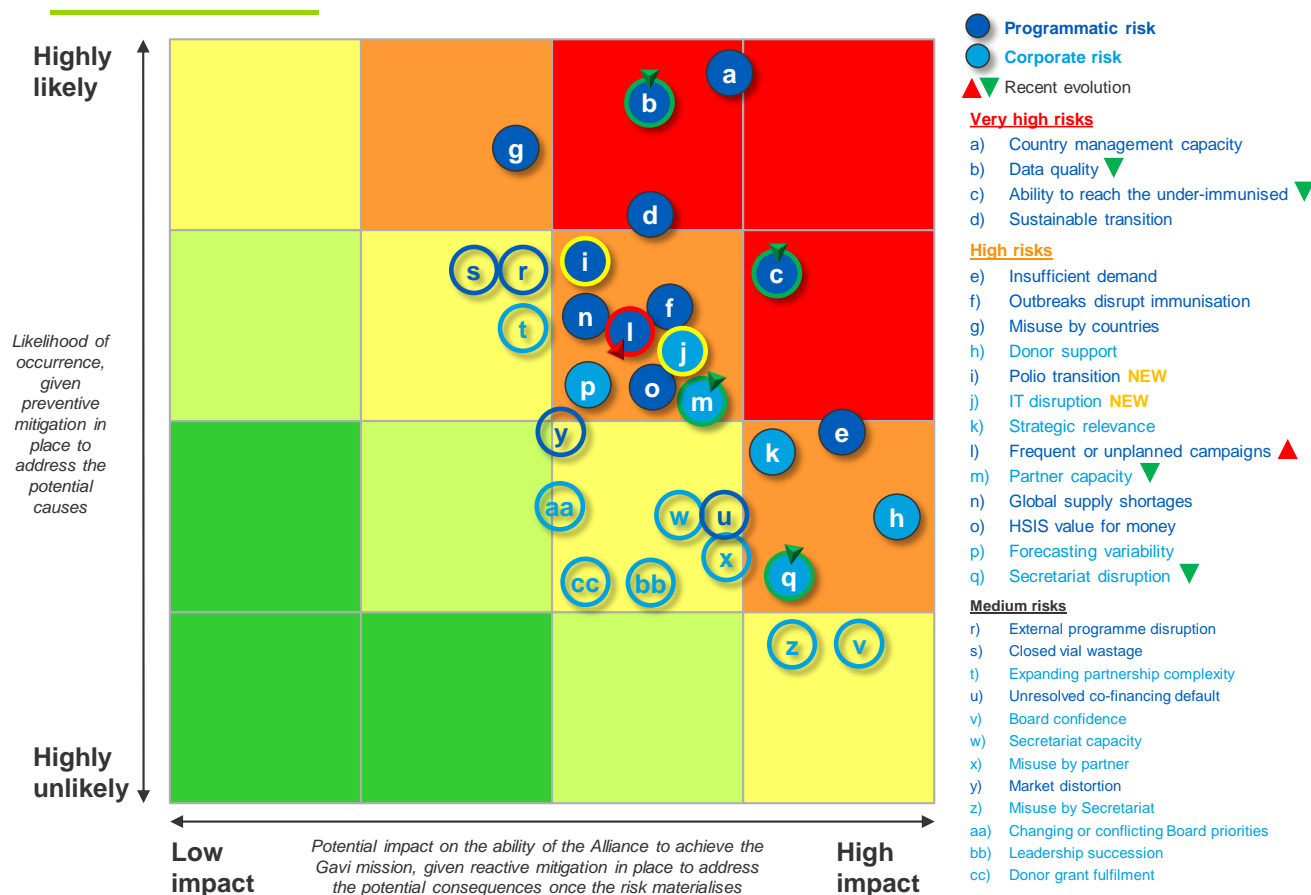
## Alliance-wide top risks summary

Alliance-wide top risks		Risk assessment			Risk evolution	
Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
a <b>Country management capacity</b> Many countries (continue to) have insufficient EPI capacity and capabilities to manage immunisation programmes to achieve sustainable coverage & equity	<ul style="list-style-type: none"> <li>Weak existing systems and technical capabilities</li> <li>Weak management capabilities</li> <li>Insufficient human resources or retention challenges</li> <li>Insufficient prioritisation of health and immunisation</li> <li>Inadequate support from Alliance to build capacity</li> <li>External programme disruption</li> <li>Disease outbreaks disrupting immunisation</li> <li>Political change (devolution)</li> </ul>	VH		OUTSIDE		
b <b>Data quality</b> Continued poor availability, quality and use of immunisation data	<ul style="list-style-type: none"> <li>Data quality not routinely monitored</li> <li>Weaknesses in data and measurement systems</li> <li>Many fragmented initiatives without measurable outcomes</li> <li>Donor-driven activities not country-owned</li> <li>Not planned and implemented to ensure data for action</li> </ul>	VH		OUTSIDE		
c <b>Ability to reach the under-immunised</b> The Alliance is unable to achieve equitable coverage improvements by extending immunisation services to communities previously unreachd	<ul style="list-style-type: none"> <li>Poor data to find and target the unreachd</li> <li>Inadequate supply and cold chains into remote areas</li> <li>Insufficient health care workers</li> <li>Lack of demand in underserved communities</li> <li>Lack of political commitment and health budgets</li> </ul>	VH		OUTSIDE		
d <b>Sustainable transition</b> Some countries fail to sustain progress of their immunisation programmes after transition	<ul style="list-style-type: none"> <li>Lack of (subnational) ability/capacity/fiscal space</li> <li>Poor preparation for transition by Alliance</li> <li>Insufficient prioritisation of health and immunisation</li> <li>Overreliance on external support</li> <li>External programme disruption (economic, outbreak)</li> <li>Lack of access to global markets and expertise</li> </ul>	VH		SOMEWHAT OUTSIDE		
e <b>Insufficient demand</b> Significant drop or insufficient increase in vaccine demand due to hesitancy and prioritisation	<ul style="list-style-type: none"> <li>Lack of knowledge / social norms</li> <li>Mistrust or fear (due to safety issue or hesitancy)</li> <li>Not actively prioritised / complacency</li> <li>Poor access to convenient and acceptable health services</li> </ul>	H		SOMEWHAT OUTSIDE		
f <b>Outbreaks disrupt immunisation</b> Sizeable outbreaks of infectious disease disrupt programmes in many Gavi-supported countries	<ul style="list-style-type: none"> <li>Low population immunity</li> <li>Lack of capacity/tools to detect, prevent and respond</li> <li>Population behaviour</li> </ul>	H		BROADLY WITHIN		
g <b>Misuse by countries</b> Deliberate misuse of Gavi support in many Gavi-supported countries	<ul style="list-style-type: none"> <li>Culture of gifts/corruption</li> <li>Opportunity for personal gain</li> <li>Weak monitoring/deterrence</li> <li>Weak institutions / systems</li> </ul>	H		SOMEWHAT OUTSIDE		
h <b>Donor support</b> Significant reduction in donor support to Gavi	<ul style="list-style-type: none"> <li>Reduction in development budgets</li> <li>Competing priorities in development</li> <li>Competing priorities within health</li> <li>Loss of donor confidence in Gavi</li> </ul>	H		SOMEWHAT OUTSIDE		

Alliance-wide top risks		Risk assessment			Risk evolution	
Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
i <b>Polio transition</b> Loss of immunisation-critical public health capacity in Gavi countries due to the winding-down of polio eradication operations	<ul style="list-style-type: none"> <li>Large reliance on GPEI-funded staff and assets</li> <li>Weak national systems</li> <li>Delayed transition plans</li> <li>Incomplete polio asset mapping</li> </ul>	H		SOMEWHAT OUTSIDE	NEW	
j <b>IT disruption</b> Critical information systems or data significantly compromised by cyber-attack or technology failure	<ul style="list-style-type: none"> <li>Cyber-attack, phishing and malware</li> <li>Internal or external data breach</li> <li>Systems failure and data loss</li> </ul>	H		SOMEWHAT OUTSIDE	NEW	
k <b>Strategic relevance</b> Gavi becomes less relevant to global development priorities	<ul style="list-style-type: none"> <li>Prioritisation of other development causes</li> <li>Inability to remain innovative and adapt</li> <li>Reduced faith in Gavi's capacity to deliver</li> <li>Growing portion of unmet immunisation needs outside Gavi countries</li> </ul>	H		SOMEWHAT OUTSIDE		
l <b>Frequent or unplanned campaigns</b> Frequent or unplanned mass vaccination campaigns undermine capacity of governments to manage routine health and immunisation services	<ul style="list-style-type: none"> <li>Periodic very large cash inflows for campaigns</li> <li>Front line workers diverted to implement campaigns</li> <li>Management capacity diverted to manage campaigns</li> <li>Infrastructure (e.g., supply chain, transport) repurposed for campaigns</li> <li>Poor planning and management undermine quality of the campaign, resulting in low coverage</li> </ul>	H		OUTSIDE		
m <b>Partner capacity</b> Sum of comparative advantages of Alliance partners is inadequate to effectively deliver required technical support to countries	<ul style="list-style-type: none"> <li>Lack of alignment and coordination</li> <li>Lack of capacity / expertise</li> <li>Lack of availability</li> </ul>	H		BROADLY WITHIN		
n <b>Global supply shortages</b> Shortages in the global vaccine supply affect Gavi-supported countries	<ul style="list-style-type: none"> <li>Manufacturing capacity inadequate to meet demand</li> <li>Unable to meet country presentation preference</li> <li>Lack of supply security</li> <li>External disruption</li> </ul>	H		SOMEWHAT OUTSIDE		
o <b>HSIS value for money</b> HSIS investments do not materially improve programmatic outcomes	<ul style="list-style-type: none"> <li>Key bottlenecks not addressable by HSIS</li> <li>HSIS grants not designed to target key bottlenecks</li> <li>HSIS grants duplicative with other donor funding</li> <li>HSIS grants not large enough to have significant impact</li> <li>HSIS not disbursed in timely fashion</li> <li>Programmes funded by HSIS not well-managed</li> <li>Misuse of HSIS resources</li> </ul>	H		BROADLY WITHIN		
p <b>Forecasting variability</b> Gavi forecasting variability driving inappropriate decision-making	<ul style="list-style-type: none"> <li>Uncertainty over vaccine demand</li> <li>Financial uncertainties (e.g., prices, FX)</li> <li>Complexity of process</li> <li>Sub-optimal systems</li> </ul>	H		BROADLY WITHIN		
q <b>Secretariat disruption</b> Significant disruption of Secretariat operations	<ul style="list-style-type: none"> <li>Catastrophic event</li> <li>Security threats and kidnapping</li> <li>Departure of large number of key staff</li> </ul>	H		BROADLY WITHIN		



## Alliance top risks ranked against likelihood and impact 2018 residual risk exposure, taking into account existing mitigation



The risk exposure heat map above depicts the 2018 top risks in the red and orange zones on two dimensions, likelihood of occurrence and potential impact. These ratings represent the residual exposure to these risks, taking into account the effectiveness of existing mitigation strategies to prevent these risks from occurring (thereby reducing the likelihood), as well as to detect and be prepared to react once they materialise (thereby reducing the potential impact). Risks are not strictly ranked within each segment as any ranking is subjective depending on how the relative importance of impact and likelihood are weighted. The next segment of risks in the yellow zone are medium risks (depicted with hollow circles), shown for comparison purposes only and not designated as top risks. The Secretariat also maintains a register containing a broader set of lower risks and their associated mitigation strategies, which are identified and managed at team level. The levels of some individual risks have evolved since last year's report as illustrated by the arrows next to each top risk.

Annex III shows the trajectory of the evolved top risks since last year in more detail. Annex IV contains a detailed description of each top risk, existing mitigation, current exposure and risk appetite. The major changes since last year are summarised below:

**b) Data quality ▼** – The risk of continued poor availability, quality and use of immunisation data is decreasing slowly given progress in mitigation, although it remains a very high risk. Gavi continues to work with countries, core and expanded partners to strengthen the availability, quality and use of immunisation data. Up from 46% in 2016 to 73% in 2017, most Gavi countries are now at least partially compliant with Gavi data improvement requirements which seek to institutionalise data strengthening efforts. Also, the percentage of countries with discrepancies of less than 10% between national administrative coverage and point estimates from surveys is showing progress.

**c) Ability to reach the under-immunised ▼** – The risk that the Alliance is unable to achieve equitable coverage improvements by extending immunisation services to communities previously unreached is decreasing but still very high. Across all the Gavi supported countries, Gavi is closely engaging with governments and Alliance partners to increase coverage and equity (C&E). The latest WHO/UNICEF Estimates of Immunisation Coverage (WUENIC) showed that coverage with three doses of DTP-containing vaccine improved for the first time in this strategic period and the new Board approved indicator for geographic equity showed a five percentage point improvement in the average proportion of districts with DTP3 coverage over 80%. Most Gavi countries have made steady progress over recent years in extending service provision and reaching the under-immunised. However, fragile countries have seen coverage stagnate.

**e) Insufficient demand (*redefined*)** – This risk was previously called “vaccine confidence” but has been reframed to better reflect the broader risk of a significant drop or insufficient increase in vaccine demand due to hesitancy and prioritisation. Demand for immunisation is critical to ensure that every child is immunised. Demand among some groups can be affected by vaccine hesitancy (which ranges from accepting only some vaccines to total refusal) while demand in other groups may not be sufficient for them to actively seek immunisation at the health facility as both their right and responsibility. To address this risk, the Secretariat and partners have developed a new demand generation framework which includes building vaccine confidence and trust as a central component. Partners have set up a demand hub and programming guidance has been developed to guide investments in demand-related areas, such as enhancing service quality, engaging communities and shaping social norms, (social) media monitoring and crisis management, and social and political mobilisation.

**i) Polio transition NEW** – The risk that immunisation-critical public health capacity could be lost due to the winding-down of polio eradication operations was identified as a potential top risk last year but left unranked pending further information becoming available to accurately assess Gavi’s exposure. Although there has been little further progress towards more detailed polio asset maps and final transition plans, the Secretariat and WHO have used existing best estimates to assess in which countries certain capacities and skill sets currently benefitting routine immunisation (or with the potential to do so) would be particularly at risk. Gavi’s current exposure to this risk varies by country but is overall high. It exists particularly in a small number of fragile countries where the footprint of GPEI is relatively large and national systems are very weak. Chad, Somalia and South Sudan have been assessed as very high risk, and DRC, Ethiopia and Sudan as high risk. At present, the three endemic countries (Afghanistan, Nigeria and Pakistan) will have their GPEI funding maintained beyond 2019, so assets are not at immediate risk. In most other countries, routine immunisation programmes are less reliant on polio assets, but polio transition may impact specific capacities, particularly in disease surveillance. There continues to be a need to obtain more granular information to help validate the activities affected by polio transition, including understanding what activities polio staff are currently undertaking and identifying skilled polio personnel to be repurposed to fully support routine immunisation. WHO has already intensified efforts to do asset mapping and understand better, country by country, the extent that polio assets might be contributing to routine immunisation, as well as developing a roadmap to maintain surveillance, the flagship of the GPEI polio eradication.

**j) IT disruption NEW** – The risk that critical information systems or data become significantly compromised by a cyber-attack or technology failure, has been added as a dedicated top risk and separated from the broader Secretariat disruption risk (which previously also included an IT element). This reflects the external threat of cyber-attacks, including ransomware, phishing and malware, continuing to increase globally, the Secretariat increasingly relying on technology, including plans for a large-scale implementation of new financial and grant management systems, and recent internal audits having found opportunities for improvement in policies and practices, including strengthening disaster recovery processes and technical capabilities along with increasing the maturity of cyber-security technologies and approaches. A significant IT systems failure, data loss or sensitive data breach could happen due to cyber-attacks, internal or external data leaks, technology glitches,

or new system implementation challenges. This could interrupt the Alliance's operations for a prolonged period of time, e.g. due to an inability to maintain communications and coordination internally and externally, an inability to complete disbursements to countries, partners or employees, or an inability to approve, manage, and monitor grants. It could also result in financial fraud or exploitation. Beyond its direct impact, it can lead to reputational impact and erode stakeholder trust.

**l) Frequent or unplanned campaigns ▲** – The risk that frequent or unplanned mass vaccination campaigns may undermine capacity of governments to manage routine immunisation services has further increased (and is now outside risk appetite), given the growing number of countries conducting periodic campaigns and continued challenges with planning and conducting high quality campaigns, which has the potential to disrupt routine immunisation services. MCV1 coverage in the Gavi 68 countries has remained unchanged at 78% during 2015-2017, and with MCV1 coverage determining the frequency of campaigns, several countries appear to be stuck in a cycle of low routine immunisation coverage and repeated vaccination campaigns with inadequate coverage.

**m) Partner capacity ▼** – The risk that the sum of comparative advantages of Alliance partners is inadequate to effectively deliver required technical support to countries has decreased and is now brought within risk appetite, given that the Partners' Engagement Framework (PEF) model has focussed on delivering more partner capacity directly to countries (with now over 200 PEF funded staff providing technical assistance at country level), and further enhanced the effectiveness, efficiency and transparency of collaboration with core partners. Core partners (WHO, UNICEF, World Bank and CDC) remain the prime recipients of PEF funding, with WHO and UNICEF receiving 79% of core funding. However, in 2017, 43 expanded partners (including local institutions in Mauritania, Pakistan, Kenya and Senegal) and 30 private sector partners were engaged, bringing new areas of comparative advantage. Gavi is continuing to empower countries to assess their technical assistance needs and the quality of technical assistance provided, as well as expanding the pool of providers including local institutions, where appropriate.

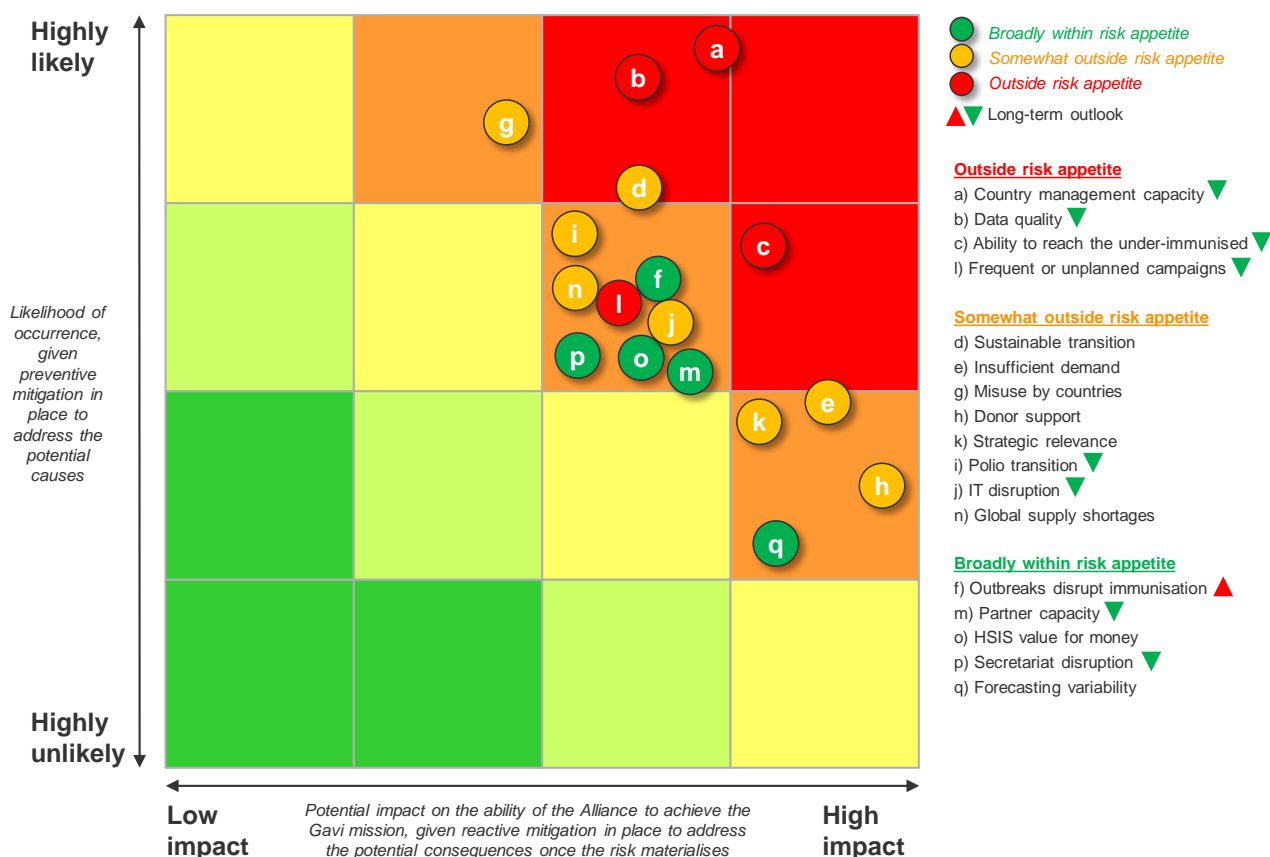
**q) Secretariat disruption ▼** – The risk of significant disruption to Secretariat operations was temporarily elevated due to the approaching move to the Global Health Campus and has now significantly decreased, following a successful move, and further due to the technology drivers of disruption having been taken out of this risk and included in the separate "IT disruption" risk. The Secretariat has now also started developing a crisis management framework with emergency response plans and recovery arrangements to ensure crisis management and business continuity after a crisis. Also, following this year's #metoo disclosures and the scandals in the aid sector regarding sexual exploitation, abuse and harassment, Gavi has assessed its exposure to such risks as low being a small Secretariat without country presence. There is a clear code of conduct, a whistle-blower hotline and ombudsman allowing issues to be raised anonymously and addressed, and explicit language on sexual exploitation and abuse has now been included in contracts with counterparts.

### 2.3. Gavi's willingness to accept the current top risk exposures

Being exposed to a high likelihood and/or potential impact of a risk can be acceptable, even if this does not mean actual occurrence of the risk is desirable. This can be because the downside of the risk, if it were to materialise, is manageable or acceptable in light of the rewards being pursued, because exposure to the risk is required to achieve Gavi's mission, or because the costs of mitigation or trade-offs with other risks are deemed too high. As per Gavi's Risk Appetite Statement (see Annex II), the Alliance embraces the need to take programmatic risk given its ambitious mission and operating model, but has a lower appetite for organisational risks impacting Alliance processes, systems and management, as well as for fiduciary oversight and control, and brand and stakeholder confidence.

## Willingness to accept current top risk exposures

### Actual exposures reviewed against aspirational risk appetite



In order to compare Gavi's actual risk exposure (as presented in the previous section) with risk appetite (i.e. the willingness to accept these exposures), the Secretariat has interpreted how the high-level statement translates into an appetite for each of the Alliance's top risks as described below (and in more detail in Annex IV). As depicted in the risk appetite heat map above, the top risks have been classified in three risk appetite categories where risks are clearly outside risk appetite (i.e. current exposure is not acceptable), somewhat outside risk appetite (requires attention), and within risk appetite (current exposure is acknowledged and accepted). Where current exposures are not in line with the Board's risk appetite, further or more intensive mitigation measures may be required to get exposure (over time) within risk appetite (e.g. by enhancing existing or introducing new mitigation measures, changes in Gavi strategy or policies, or by ending certain activities that expose the Alliance to risk). Alternatively, the Board could choose to increase its risk appetite and acknowledge being exposed.

The arrows next to each top risk in the risk appetite heat map show the expected long-term outlook<sup>3</sup> of the risk exposures, which can increase (e.g. due to trends in inherent or external risk factors), or decrease (due to trends in risk factors and / or due to the expected effect of mitigation measures). Being outside of risk appetite for a period of time can be acceptable if the expected trajectory is in the right direction, and especially if this is due to the inherent risks in our business which are to some extent outside the Alliance's control or required to achieve Gavi's mission. However, risks that are systematically outside appetite should continue to be revisited

<sup>3</sup> Previously, Gavi has focused its risk assessment on Gavi-eligible countries. This means that many risks were inherently increasing over time as stronger countries transition out of support. With the Board's assertion that the Alliance is concerned with performance after countries transition and approval of post-transition engagement, the risk outlook is now assessed across the full 68 Gavi countries.

and trigger a debate on whether this requires a more ambitious approach or radical change to the way the Alliance mitigates such risks, or whether a more realistic risk appetite should be set.

### **Top risks outside risk appetite – requiring intensive mitigation efforts**

**a) Country management capacity** – Although the Alliance has a moderately high appetite for risks associated with operating in countries with limited capacity, given this is a requirement of its mission (particularly in very poor or fragile countries), it cannot accept a very high risk that EPI management capacity does not improve across its portfolio. Having sufficient national and subnational capacity to manage immunisation programmes and funding is crucial for countries to achieve improvements in coverage and equity, and to be ready for a sustainable transition out of Gavi support. Although there is progress in mitigation, current exposure to this risk remains very high as new approaches are being tested and real impact has yet to be measured – sustainable capacity-building efforts take time and can only be measured over several years, however we expect exposure to come down slowly going forward. Broader efforts across the health sector, in particular on public financial management, are necessary for more sustainable mitigation (e.g. in collaboration with other partners like the World Bank and the Global Fund). As the current exposure remains outside risk appetite, this risk continues to require intensive mitigation efforts.

**b) Data quality** – Although the Alliance has a moderately high appetite for risks associated with working in settings with relatively weak data systems, given this is a requirement of its mission (particularly in very poor or fragile countries), it cannot accept a very high risk that the data availability, quality and use does not improve across its portfolio. Given that immunisation now reaches the vast majority of the population in Gavi countries, achieving coverage and equity goals increasingly requires a “precision public health” approach – using robust data to identify where unreached populations are and measure and evaluate the impact of interventions to reach them. Furthermore, the Alliance is dependent on data for decision-making at all levels, planning of supply and delivery of vaccines, allocation of Gavi support, and the ability to accurately measure and demonstrate impact. Given the progress in mitigation, current exposure to this risk is decreasing slowly, although it remains a very high risk and the impact of these mitigation efforts – both building more robust data systems and creating a culture of data use and data-driven decision-making – take time and country level political will, and the Alliance’s investment in data is limited compared with the level of inherent risk. As the current exposure is outside risk appetite, this risk continues to require intensive mitigation efforts.

**c) Ability to reach the under-immunised** – The Alliance has a low appetite for the risk of not being able to achieve equitable coverage improvements, since this is key to its mission. It recognises that improving coverage and equity requires working in complex settings where it is necessary to take risks in order to reach the most disadvantaged populations and that this often requires political (as well as technical) change which goes beyond the immunisation programme. Current exposure to this risk is decreasing but still very high. Most Gavi countries have made steady progress over recent years in extending service provision and reaching the under-immunised. However, fragile countries have seen coverage stagnate. This is partly due to the acute problems they face and also because of rapid population growth. This confirms the consensus reached at the Board Retreat earlier this year that there is good progress in stronger countries but more challenges in fragile countries, and the Alliance should look further into how it can differentiate its approach and tailor it to address the challenges of fragile countries (or countries with fragility at sub-national levels), including potentially a different risk appetite in such countries. While progress is being made in a number of countries, sustainable change is a long-term process and it is not yet clear that the pace of change is sufficient to secure the Alliance’s coverage and equity goals by 2020 – there remain many barriers to progress including many over which the Alliance has limited influence (e.g., national investments in HR). As the current exposure is outside risk appetite, this risk continues to require intensive mitigation efforts.

**l) Frequent or unplanned campaigns** – The Alliance has a low appetite for the risk of immunisation campaigns undermining the effectiveness or sustainability of routine immunisation – although risk appetite is

somewhat higher in the case of emergency campaigns responding to disease outbreaks. Continued reliance on campaigns undermines the goal of strengthening health systems and durably improving population coverage. However, current exposure to this risk has further increased (and is now outside risk appetite), given the growing number of countries conducting periodic campaigns and continued challenges with planning and conducting high quality campaigns, which has the potential to disrupt routine immunisation services. This Board will therefore discuss a proposal for how to better balance incentives for Gavi supported measles and rubella immunisation activities. In parallel, WHO and SAGE guidance is necessary to break the cycle of periodic nationwide SIAs. As the current exposure is outside risk appetite, this risk continues to require intensive mitigation efforts.

#### Top risks somewhat outside risk appetite – requiring attention

Eight top risks are currently assessed as being somewhat outside risk appetite. Three of these are rated high – and somewhat outside appetite – mainly because of their high potential impact, while their likelihood of occurrence is lower. This is the case for **e) Insufficient demand**, **h) Donor support** and **k) Strategic relevance**. Since it is generally harder to mitigate the impact of a risk than its likelihood, such exposure may be more acceptable. However, it is important to monitor closely whether these risks increase in likelihood, which may move them more clearly outside appetite and justify further and more intensive mitigation efforts. Another four are somewhat outside appetite on the overall portfolio level, with variable levels of risk in underlying individual countries or markets. This is the case for **d) Sustainable transition**, **g) Misuse by countries** and **n) Global supply shortages**. The remaining risks **i) Polio transition** and **j) IT disruption** are currently high but expected to decline due to ongoing mitigation efforts.

#### Top risks broadly within risk appetite – to be monitored

Exposures for the remaining group of top risks fall broadly within risk appetite. These are **f) Outbreaks disrupt immunisation**, **m) Partner capacity**, **o) HSIS value for money**, **p) Secretariat disruption**, and **q) Forecasting variability**. It should be noted however that the long-term outlook for **f) Outbreaks disrupt immunisation** is expected to increase. It is important to continue to monitor whether the risk will move at some point more outside risk appetite, and to discuss whether further mitigation is required before that point since implementing it typically takes time.

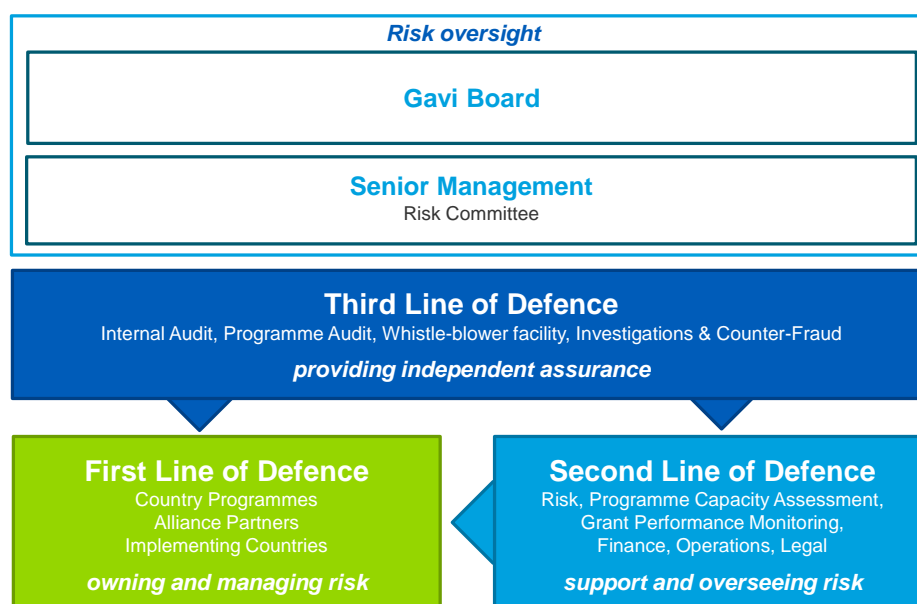
Annex IV contains a detailed description of each top risk and how current exposure compares to risk appetite.

## Annex I – Gavi’s risk management and assurance model

Risk is everyone’s responsibility and risk management is an integral part of Gavi operations. Everyone working towards the Gavi mission is expected to pro-actively identify, assess, and manage risks. As stated in Gavi’s Risk Policy:

- The Gavi Board determines Gavi’s risk appetite, validates that effective risk management processes are established, and oversees that the most significant risks are being managed within Gavi’s risk appetite.
- The Secretariat translates the risk appetite into appropriate strategies and processes intended to anticipate and respond to risk, and implements these processes. Secretariat staff are responsible for identifying and managing risk in their daily work.
- Alliance partners are responsible for managing risks involved with Gavi activities and for alerting the Secretariat of risks that could affect Gavi’s mission.
- Implementing countries manage risks to the results being pursued with Gavi-funded programmes, and report these risks encountered in implementation.

Gavi has structured its risk management, control and assurance functions according to the Three Lines of Defence model, ensuring clear and distinct roles and objective checks, balances and controls. Its underlying premise is that, under the oversight and direction of senior management and the Board, three separate groups (or lines of defence) within the organisation are necessary for effective management of risk and control.

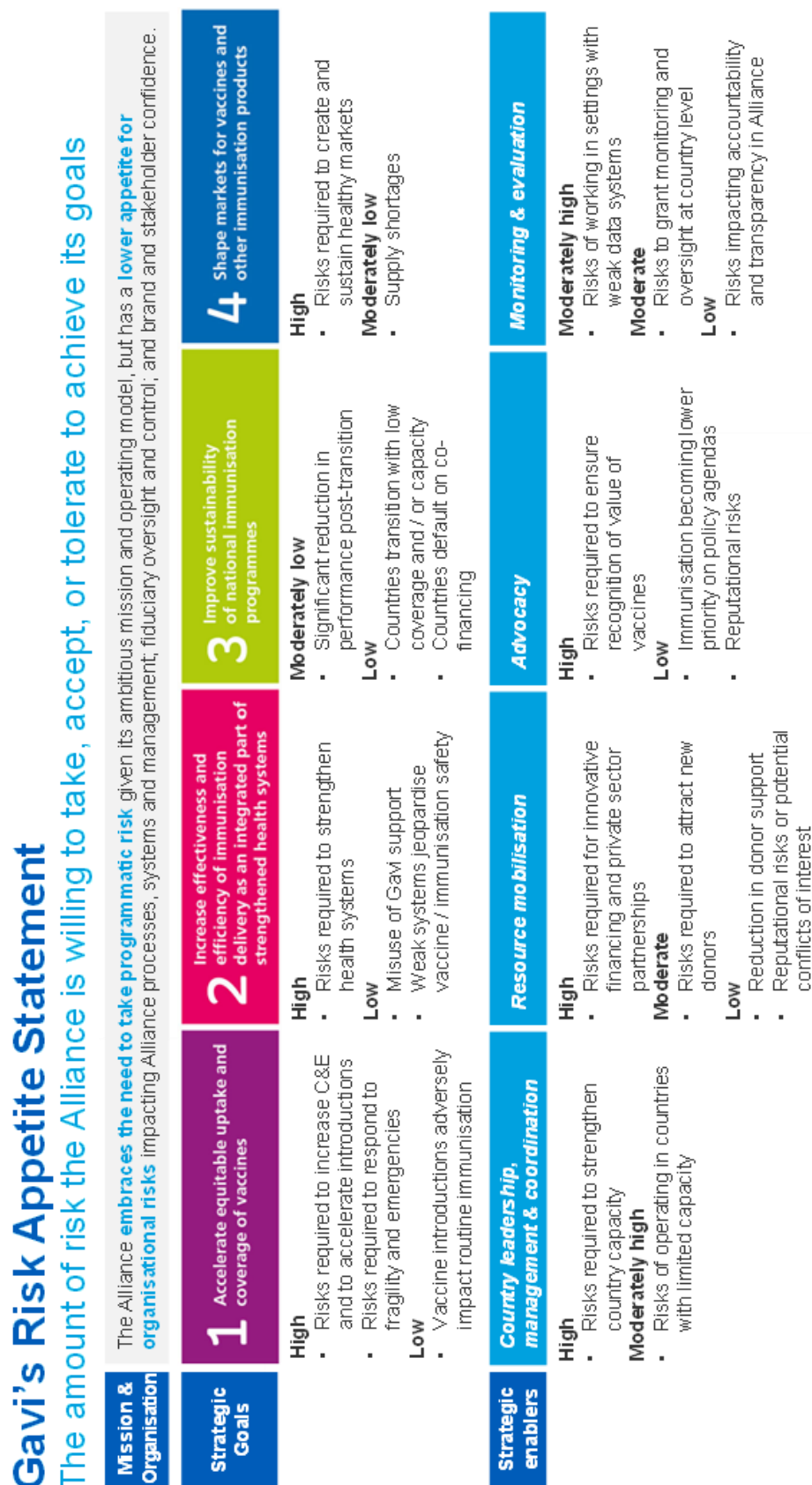


The responsibilities of each of the groups (or “lines”) are:

- **First line: owning and managing risk**  
Primary ownership sits with the business and process owners whose activities create and/or manage the risks that can facilitate or prevent an organisation’s objectives from being achieved. This includes taking the right risks. The first line owns the risk, and the design and execution of the organisation’s controls to respond to those risks.  
*Constituted by Country Programmes working with Alliance partners and implementing countries*
- **Second line: overseeing risk in support of management**  
The second line is put in place to support management by bringing specialised expertise, and coordinating, monitoring and overseeing risk management alongside the first line to help ensure that risk and control are effectively managed. While separate from the first line, they are still under the control and direction of senior management.  
*Constituted by the Risk function, Programme Capacity Assessment, Grant Performance Monitoring, Finance, Operations, and Legal*
- **Third line: providing independent assurance**  
An independent third line is providing objective assurance to the Board and senior management on the effectiveness of risk management and control by both the first and second line. Importantly, the third line has an independent reporting line to the Board – as well as senior management – to ensure its independence and objectivity.  
*Constituted by Audit & Investigations (Internal Audit, Programme Audit, Investigations & Counter-Fraud)*

## Annex II – Gavi’s Risk Appetite Statement

Gavi’s Risk Appetite Statement defines on a broad level the amount of risk the Alliance is willing to take, accept, or tolerate in each area of its strategy.

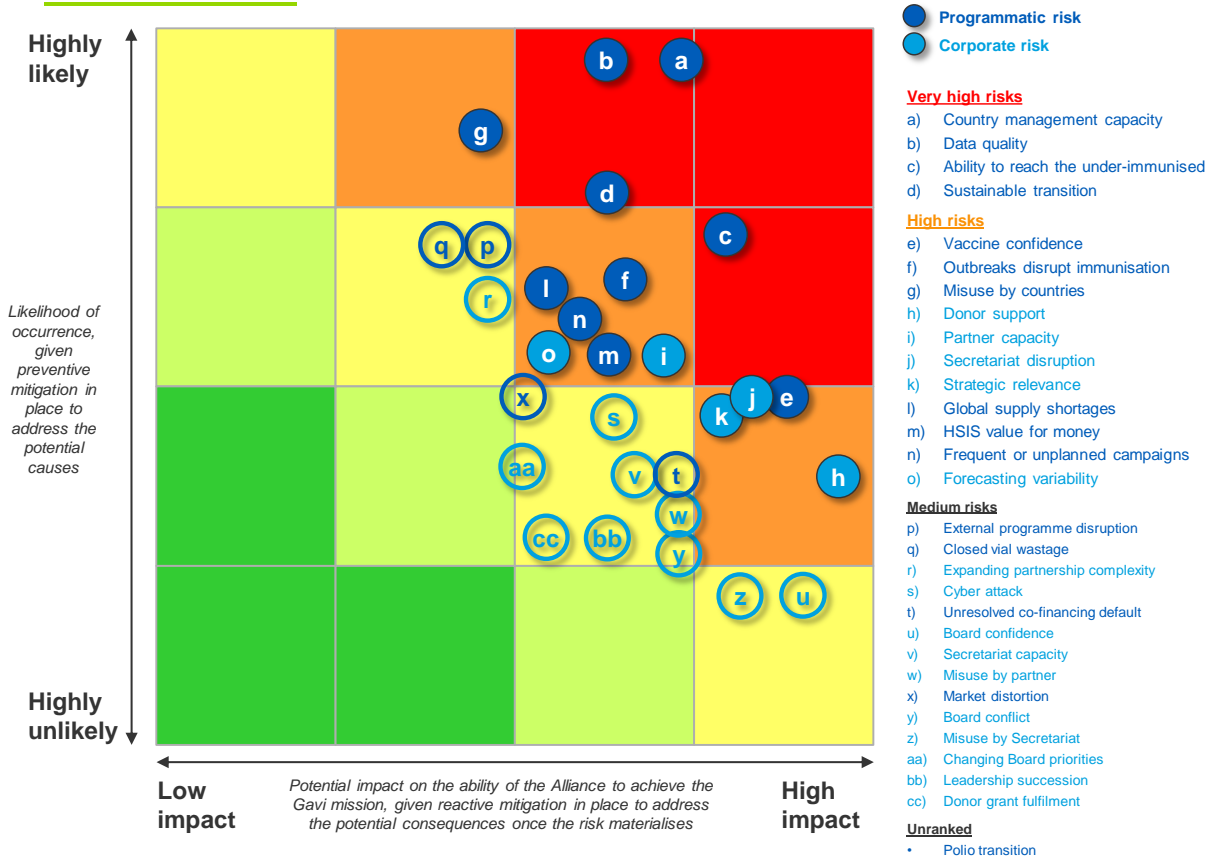


See for the full statement: <http://www.gavi.org/library/gavi-documents/policies/risk-appetite-statement/>

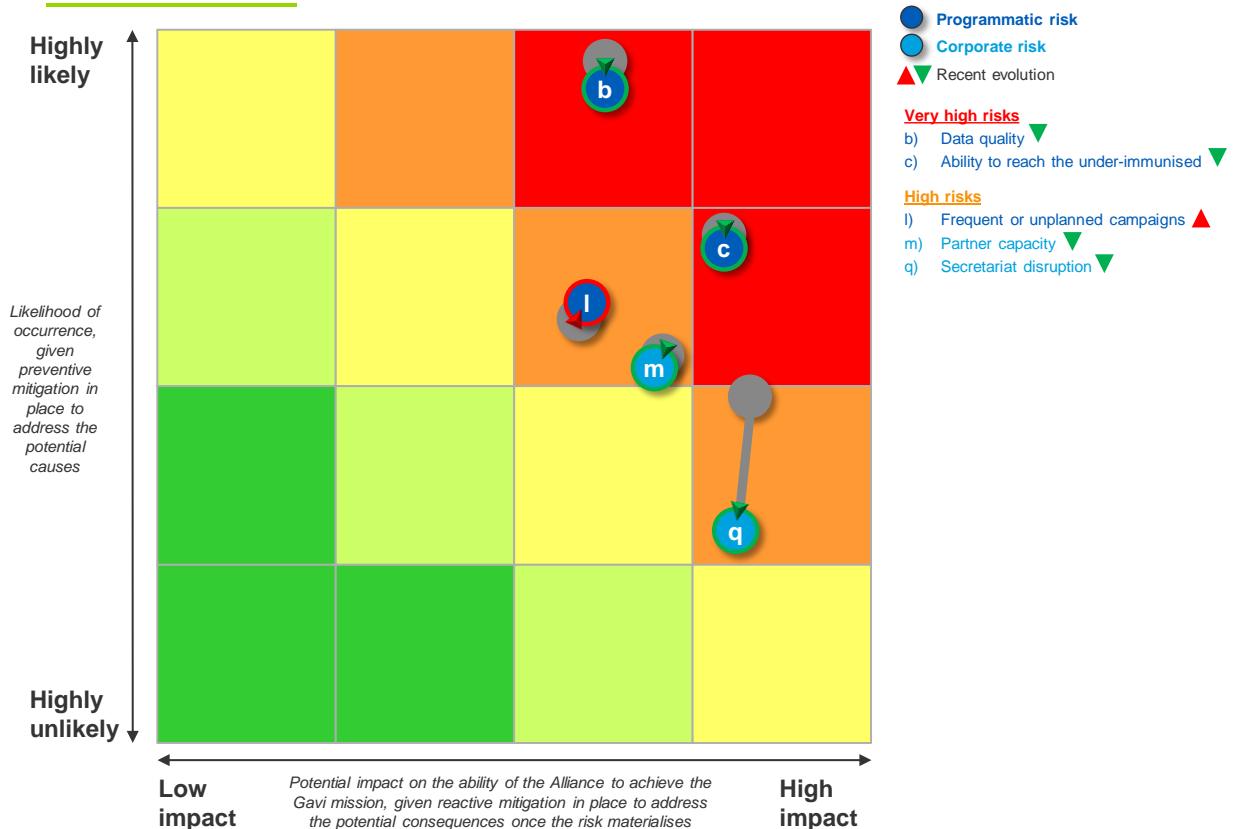


Annex III – Top risk profile evolution since last year

Alliance top risks ranked against likelihood and impact  
2017 residual risk exposure, taking into account existing mitigation



Trajectory of the evolved top risks since last year



## Annex IV – Individual top risk descriptions

### a) Country management capacity

*Many countries (continue to) have insufficient EPI capacity and capabilities to manage immunisation programmes to achieve sustainable coverage & equity*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<b>a</b> <b>Country management capacity</b> Many countries (continue to) have insufficient EPI capacity and capabilities to manage immunisation programmes to achieve sustainable coverage & equity	<ul style="list-style-type: none"> <li>Weak existing systems and technical capabilities</li> <li>Weak management capabilities</li> <li>Insufficient human resources or retention challenges</li> <li>Insufficient prioritisation of health and immunisation</li> <li>Inadequate support from Alliance to build capacity</li> <li>External programme disruption</li> <li>Disease outbreaks disrupting immunisation</li> <li>Political change (devolution)</li> </ul>			<b>OUTSIDE</b>		

The Alliance is working in the poorest countries in the world, many of which face fragility challenges. Naturally, many Gavi countries have weak capacity, even more so at subnational levels. Existing capacity can also easily be disrupted due to instability, shocks or political change (such as devolution), or due to retention challenges. Developing sufficient and robust national and subnational capacity to manage immunisation programmes is crucial for countries to achieve improvements in coverage and equity, manage Gavi support, and to be ready for a sustainable transition out of Gavi support. The impact of (continued) weak capacity in areas such as leadership, management and coordination, technical and policy decision-making, financial management, and programme implementation cuts across all in-country work of the Alliance and can increase a number of other risks, such as misuse of Gavi support and poor data quality.

Following the evaluation of Alliance technical assistance (TA) to countries (which found that TA funded by Gavi was not clearly laying out whether it was for short-term gap-filling instead of for transfer of knowledge and sustainable capacity building), 2018 TCA guidance now includes a specific section on 'Transfer of skills' detailing the objective and approach for it, and the PEF Management Team oversees TA delivery in 20 priority countries with continued attention to lessons learned based on independent reviews. Gavi furthermore continues to assess capacity-building needs that can be addressed with Gavi support through Joint Appraisals, Programme Capacity Assessments, Effective Vaccine Management assessments, Transition Assessments and country visits. Furthermore, good progress is made in scaling up the innovative Leadership, Management, and Coordination (LMC) approach, now having contracted expanded partners for managerial assistance in 34 countries (14 new countries in the last 6 months). The pool of prequalified partners for LMC has been expanded, with special attention to mobilising local partners. Sub-national efforts are starting and key countries with broad challenges (DRC, Haiti, Niger, and Nigeria) are receiving enhanced and more holistic LMC support. Financial management capacity has not been a major focus until recently but is increasingly a priority given efforts to further mitigate fiduciary risk (this will be further discussed in the Risk Management item at this Board). Lastly, an LMC Results Framework is being developed to assess progress and impact, and an institutional capacity assessment survey is now being carried out on an annual basis across all Gavi countries (and captured in the corresponding Alliance KPI).





Although there is progress in mitigation, current exposure to this risk remains very high as new approaches are being tested and real impact has yet to be measured – sustainable capacity-building efforts take time and can only be measured over several years, however we expect exposure to come down slowly going forward. Broader efforts across the health sector, in particular on public financial management, are necessary for more sustainable mitigation (e.g. in collaboration with other partners like the World Bank and the Global Fund).

Current exposure remains outside risk appetite and therefore continues to require intensive mitigation efforts. Although the Alliance has a moderately high appetite for risks associated with operating in countries with limited capacity, given this is a requirement of its mission (particularly in very poor or fragile countries), it cannot

accept a very high risk that EPI management capacity does not improve across its portfolio. Having sufficient national and subnational capacity to manage immunisation programmes and funding is crucial for countries to achieve improvements in coverage and equity, and to be ready for a sustainable transition out of Gavi support.

## b) Data quality

### *Continued poor availability, quality and use of immunisation data*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
b Data quality Continued poor availability, quality and use of immunisation data	<ul style="list-style-type: none"> <li>Data quality not routinely monitored</li> <li>Weaknesses in data and measurement systems</li> <li>Many fragmented initiatives without measurable outcomes</li> <li>Donor-driven activities not country-owned</li> <li>Not planned and implemented to ensure data for action</li> </ul>			OUTSIDE		

Many Gavi-supported countries have weak systems and capacity to generate, report and use data, including in critical areas such as programme data and disease surveillance. Improvements are critical to deliver on all four of Gavi's strategic goals, as well as for strong programme monitoring and evaluation. Persistent challenges with the quality and use of data can lead to misinformed decision-making at all levels, from poor planning of supply and delivery of vaccines, to misallocation of Gavi support, and the inability to accurately measure and demonstrate impact. It also increases a number of other risks, such as misuse of Gavi support, closed-vial wastage, disease outbreaks, and insufficient demand.

Gavi continues to work with countries, core and expanded partners to strengthen the availability, quality and use of immunisation data. The Secretariat has integrated an enhanced focus on data in its grant management processes and partners have it incorporated into their technical assistance and capacity-building initiatives. Data Strategic Focus Area investments, through PEF TCA, LMC, and HSS grants, continue to support countries transition from use of paper-based records to electronic district health information systems (DHIS2 is now implemented in more than 50 countries with immunisation programme data integrated in over 30 countries), expand use of digital health tools (e.g., work with NexLeaf to scale-up temperature monitoring of cold chain equipment) and strengthen the review and analysis of more real-time and sub-national immunisation coverage data. The Secretariat has started to develop differentiated approaches based on country typologies. Furthermore, additional special investments are developed to support a revision to the WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) methodology to improve coverage estimates, enhance data triangulation both in-country and in the Secretariat to improve data reliability, strengthen collaboration and alignment of investments with other global health players (e.g., the Global Fund and the Health Data Collaborative) and engage private sector expanded partners to help countries access cutting edge data solutions. This Board will also discuss support for Yellow Fever surveillance, another critical data system.





Given the progress in mitigation, current exposure to this risk is decreasing slowly, although it remains a very high risk and the impact of these mitigation efforts – both building more robust data systems and creating a culture of data use and data-driven decision-making – take time and country level political will, and the Alliance's investment in data is limited compared with the level of inherent risk. Up from 46% in 2016 to 73% in 2017, most Gavi countries are now at least partially compliant with Gavi data improvement requirements which seek to institutionalise data strengthening efforts. Also, the percentage of countries with discrepancies of less than 10% between national administrative coverage and point estimates from surveys is showing progress.

Current exposure remains outside risk appetite and therefore continues to require intensive mitigation efforts. Although the Alliance has a moderately high appetite for risks associated with working in settings with relatively weak data systems, given this is a requirement of its mission (particularly in very poor or fragile countries), it cannot accept a very high risk that the data availability, quality and use does not improve across its portfolio.

Given that immunisation now reaches the vast majority of the population in Gavi countries, achieving coverage and equity goals increasingly requires a “precision public health” approach – using robust data to identify where unreached populations are and measure and evaluate the impact of interventions to reach them. Furthermore, the Alliance is dependent on data for decision-making at all levels, planning of supply and delivery of vaccines, allocation of Gavi support, and the ability to accurately measure and demonstrate impact.

### c) Ability to reach the under-immunised

*The Alliance is unable to achieve equitable coverage improvements by extending immunisation services to communities previously unreached*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<b>c</b> <b>Ability to reach the under-immunised</b> The Alliance is unable to achieve equitable coverage improvements by extending immunisation services to communities previously unreached	<ul style="list-style-type: none"> <li>Poor data to find and target the unreached</li> <li>Inadequate supply and cold chains into remote areas</li> <li>Insufficient health care workers</li> <li>Lack of demand in underserved communities</li> <li>Lack of political commitment and health budgets</li> </ul>			<b>OUTSIDE</b>		

Gavi’s initial focus on reducing inequities between countries by bringing new vaccines to the poorest countries has now expanded to include improving the equitable coverage of immunisation within countries in order to reach every child. This requires the extension of immunisation services to reach every community, including building out the service delivery infrastructure, supply chain, and data systems and generating demand in previously underserved communities (see also the top risk “Insufficient demand”). Reaching the under-immunised therefore depends on Gavi’s ability to identify and scale-up access for the remaining pockets of under-immunised children, who are increasingly in under-served areas such as conflict areas, remote rural communities or in urban slums. This ability can be hindered by shortages of frontline health workers, poor infrastructure including the absence of health facilities and adequate supply chains, weak programme management and accountability, poor data, weak institutional capacity, social, cultural and gender barriers, conflict, political turmoil and mass population displacement. These barriers often go beyond the immunisation programme itself, requiring political commitment to reach neglected populations that are often underserved by a broad range of public services.

Across all the Gavi supported countries, Gavi is closely engaging with governments and Alliance partners to increase coverage and equity (C&E). Gavi’s HSS grants are increasingly targeting the barriers to reaching under-immunised children, and Gavi has re-programmed or re-allocated a substantive number of grants to focus much more closely on the key drivers of C&E, such as supply chain, data and demand (~60% of proposed budget activities in HSS grants). Flexibilities under the Fragility, Emergencies and Refugees policy have been introduced to further address potential C&E bottlenecks in fragile and emergency countries. All Gavi countries now have Grant Performance Frameworks (GPFs) in place to set goals and targets for grants, monitor grant performance during implementation and to ensure faster responses to bottlenecks or challenges. Furthermore, Regional Working Groups and EPI Managers Meetings are leveraged to drive the C&E agenda forward through the wider Alliance structure. Systematic regional portfolio reviews are being carried out, and regular country calls with regional Alliance partners take place to resolve implementation bottlenecks. Key country-level challenges are being escalated more systematically to the Alliance Coordination Team (ACT) to resolve, and within the Secretariat, a team of Directors is meeting regularly to review progress in key countries to support Senior Country Managers to accelerate performance on coverage and equity.

Current exposure to this risk is therefore decreasing but still very high. The latest WHO/UNICEF Estimates of Immunisation Coverage (WUENIC) showed that coverage with three doses of DTP-containing vaccine improved for the first time in this strategic period and the new Board approved indicator for geographic equity showed a five percentage point improvement in the average proportion of districts with DTP3 coverage over 80%. Most Gavi countries have made steady progress over recent years in extending service provision and

reaching the under-immunised. However, fragile countries have seen coverage stagnate. This is partly due to the acute problems they face and also because of rapid population growth. This confirms the consensus reached at the Board Retreat earlier this year that there is good progress in stronger countries but more challenges in fragile countries, and the Alliance should look further into how it can differentiate its approach and tailor it to address the challenges of fragile countries (or countries with fragility at sub-national levels), including potentially a different risk appetite in such countries. While progress is being made in a number of countries, sustainable change is a long-term process and it is not yet clear that the pace of change is sufficient to secure the Alliance's coverage and equity goals by 2020 – there remain many barriers to progress including many over which the Alliance has limited influence (e.g., national investments in HR).

Current exposure remains outside risk appetite and therefore continues to require intensive mitigation efforts. The Alliance has a low appetite for the risk of not being able to achieve equitable coverage improvements, since this is key to its mission. It recognises that improving coverage and equity requires working in complex settings where it is necessary to take risks in order to reach the most disadvantaged populations and that this often requires political (as well as technical) change which goes beyond the immunisation programme.

#### d) Sustainable transition

*Some countries fail to sustain progress of their immunisation programmes after transition*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
d Sustainable transition Some countries fail to sustain progress of their immunisation programmes after transition	<ul style="list-style-type: none"> <li>Lack of (subnational) ability/capacity/fiscal space</li> <li>Poor preparation for transition by Alliance</li> <li>Insufficient prioritisation of health and immunisation</li> <li>Overreliance on external support</li> <li>External programme disruption (economic, outbreak)</li> <li>Lack of access to global markets and expertise</li> </ul>			SOMEWHAT OUTSIDE		

Being time-limited and catalytic, Gavi financial support to countries diminishes as their gross national income (GNI) approaches the eligibility threshold, while the share of country co-financing increases until they are fully self-financing. Countries need to be both financially and programmatically ready for a successful transition out of Gavi support to be able to sustain the gains and continue to progress after transition without Gavi financial support. This model is being tested at scale for the first time during the current strategic period with approximately 20 countries projected to have transitioned by the end of 2020. Failure to successfully transition or a regression after transition would diminish the return on Gavi's investments and could impact Gavi's reputation and the perceived viability of the model. Furthermore, it may impact manufacturers' pricing decisions for countries post-transition if they perceive a higher risk that countries will not sustain their programmes.

Gavi's Sustainability Strategic Focus Area emphasises greater and earlier engagement with every country on sustainability. Before countries enter the last phase of Gavi support, transition plans are developed based on transition assessments to address bottlenecks with tailored support to complement HSIS and PEF targeted country assistance. The fragility policy also provides flexibilities for fragile countries undergoing transition. All transitioning countries have a transition plan with active support and monitoring, supported by an increasing number of partners (e.g. UNICEF, World Bank, and CHAI). A forum for transitioning countries has been established which will bilaterally link higher capacity transitioned countries to support lower capacity transitioned countries (e.g., through the Learning Network for Transitioning Countries). Following Board-approval, initial approaches to mitigate post-transition risks in selected high-risk countries (Angola, Congo Republic and Timor-Leste) have been developed, and additional engagement modalities will be reviewed by this Board. Risks in countries still to transition (an additional 4 countries by 2020, and 8 projected for 2021-2025) continue to be monitored. A tailored transition plan has been developed for Nigeria and for Papua New Guinea intensified engagement is planned.

On a portfolio level risk exposure remains stable. By now 16 out of 20 countries projected for this strategic period have transitioned out of Gavi support and the majority perform well and present a low risk to *financial* sustainability of support introduced with Gavi. Co-financing defaults are near an all-time low (98% of countries met co-financing obligations, representing US\$ 136 million, and a payment plan is already agreed for the remaining country), and overall domestic investments per child increased. However, as identified by the Board at its Retreat in 2017, there are a number of countries at higher risk mainly due to *programmatic* underperformance and institutional capacity challenges, which are now being addressed. Despite these mitigation efforts, the risk remains very high given that with its approach to transition Gavi is a pioneer in the field.

Gavi's Risk Appetite Statement expresses a moderately low risk appetite for countries reaching the point of transition without having built sufficient financial and programmatic capacity to sustain their programmes and for significant reduction in immunisation programme performance after transition. Although the Alliance does not have an appetite for the risk of *many* countries across the portfolio failing sustainable transition, it also recognises that it cannot completely guarantee that every country is ready to transition, especially programmatically (e.g., in countries with inadequate political will or weak institutions beyond immunisation) and needs to avoid the risk of moral hazard. It is therefore willing to consider tailored approaches to support countries who are at high risk of not being ready for transition and have strong political commitment to immunisation, but is willing to consider a few countries failing where this is not the case (and therefore has a higher appetite for the risk that a *limited number of countries* may not transition successfully). Since most countries are currently on track for successful transition, with a few outliers (in terms of programmatic sustainability) which are actively addressed with tailored approaches, the current very high risk exposure for *some countries* failing sustainable transition is somewhat outside risk appetite.

## e) Insufficient demand

### *Significant drop or insufficient increase in vaccine demand due to hesitancy and prioritisation*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
e <b>Insufficient demand</b> Significant drop or insufficient increase in vaccine demand due to hesitancy and prioritisation	<ul style="list-style-type: none"> <li>Lack of knowledge / social norms</li> <li>Mistrust or fear (due to safety issue or hesitancy)</li> <li>Not actively prioritised / complacency</li> <li>Poor access to convenient and acceptable health services</li> </ul>			SOMEWHAT OUTSIDE		

Demand for immunisation is critical to ensure that every child is immunised. Demand among some groups can be affected by vaccine hesitancy (which ranges from accepting only some vaccines to total refusal) while demand in other groups may not be sufficient for them to actively seek immunisation at the health facility as both their right and responsibility. Vaccine confidence depends on trust in the effectiveness and safety of vaccines, in the system that delivers them, including the reliability and competence of the health services and health professionals, and in the motivations of policy-makers. Adverse events following immunisation (AEFIs) can also rapidly undermine confidence in vaccines. Developing countries are particularly vulnerable where they do not have capacity to respond robustly to AEFIs, especially in terms of crisis communications and social media management. Rumours and anti-vaccine sentiment, typically based on misinformation, can spread rapidly on social media and are often actively promoted by anti-vaccine movements driven by ideology, religion, false beliefs, and increasingly political or commercial motives, against which traditional vaccine science-based responses are ineffective. Gavi countries may not be well-equipped to manage a concerted anti-vaccine campaign. Populations may be particularly susceptible to negative messages about vaccines with which they are less familiar or linked to sensitive issues (e.g. HPV) or for which the disease incidence is becoming rare (e.g. polio). Active demand can be hindered by lack of knowledge about the value of vaccines, lack of prioritisation or complacency, or lack of convenient access to health facilities. In areas that have been the focus for many immunisation campaigns, households may become accustomed to services being delivered

at their doorstep and therefore less willing to actively seek immunisation at a health facility. Similarly, poor service quality, long waiting times or distance from facilities may deter some families from seeking immunisation.

A significant drop in demand for vaccines or an insufficient increase in demand among those who are not yet demanding immunisation, would have a significant impact on Gavi's ability to achieve its coverage and equity ambitions. Lack of demand can adversely impact vaccine introductions and / or coverage, which in turn leads to increased morbidity and mortality and reduced programme impact. A drop in demand or less actual demand than planned can furthermore lead to programme delays and vaccine wastage. Gavi could also face reputational challenges and Alliance staff could become the target of extreme anti-vaccine movements. Ultimately, a significant and sustained loss of demand for vaccines could affect political will and reduce support among donor and implementing countries for Gavi's mission.

To address this risk, the Secretariat and partners have developed a new demand generation framework which includes building vaccine confidence and trust as a central component. Partners have set up a demand hub and programming guidance has been developed to guide investments in demand-related areas, such as enhancing service quality, engaging communities and shaping social norms, (social) media monitoring and crisis management, and social and political mobilisation. Currently many promising interventions are being tested such as SMS reminders, building interpersonal communications skills, community monitoring and motivation, social listening and mass media approaches. To mitigate the risk of AEFIs, the Alliance only procures vaccines that have been licensed by a recognised NRA and pre-qualified by WHO and provides support for training of healthcare workers on safe immunisation practices and vaccine management, and for strengthening vaccine supply chains and cold chains. Support is also provided to strengthen NRAs and NITAGs, and for global policy and standards for vaccine pharmacovigilance. Alliance partners support AEFI monitoring and risk communications in Gavi countries, proactive media engagement and capacity building, as well as AEFI response and investigations. The Secretariat monitors vaccine hesitancy by tracking global, national and social media and more systematic and innovative global and regional approaches to social listening and media monitoring are being explored. A crisis protocol and response group stands ready in case of sudden threat escalation. Finally, the Secretariat is engaged with partners on the emerging risk of fake vaccines.

Current exposure to this risk is still high mostly in terms of potential impact. Data on reasons for under-immunised children from countries such as Nigeria and India suggest that in some areas as many as 8 or 9 children out of 10 are missed due to demand rather than supply side issues, indicating that a significant number of under-immunised children fail even to make it to the health facility. Furthermore, the growth in vaccine doses supported by Gavi over the coming years, combined with a focus on reaching remote areas with weaker health systems, increases the risk of serious AEFIs. Additionally, while anti-vaccine campaigning remains mostly contained within the US and related risks seem higher in developed countries, campaigners are seeking to target other countries and some attempts have been made to reach out internationally. Civil society organisations and Ministries of Health have highlighted a perceived growth of anti-vaccine movements in Gavi countries. The Strategic Advisory Group of Experts on Immunization (SAGE) is tracking indicators to assess vaccine hesitancy worldwide as part of the Global Vaccine Action Plan (GVAP), which showed that only seven countries reported a complete absence of hesitancy, indicating that the issue has become a truly global challenge.

The Alliance has a low appetite for the risk of a sustained decline in demand and public confidence in vaccines in implementing countries, or in donor countries where this might impact their support to Gavi. Because current exposure is high due to potential impact rather than likelihood, the risk is currently only somewhat outside risk appetite. However, it is important to monitor closely whether the risk increases in likelihood especially in Gavi

countries, which may move it more clearly outside appetite and justify further and more intensive mitigation efforts.

## f) Outbreaks disrupt immunisation

### *Sizeable outbreaks of infectious disease disrupt programmes in some Gavi-supported countries*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<b>f</b> <b>Outbreaks disrupt immunisation</b> Sizeable outbreaks of infectious disease disrupt programmes in many Gavi-supported countries	<ul style="list-style-type: none"> <li>• Low population immunity</li> <li>• Lack of capacity/tools to detect, prevent and respond</li> <li>• Population behaviour</li> </ul>			<b>BROADLY WITHIN</b>		

Outbreaks of infectious diseases are occurring with increasing frequency. This trend is driven by factors including climate change – which is increasing the range of disease-transmitting insect vectors such as mosquitoes while climate-related disasters can create the conditions for outbreaks (e.g., cholera) – and urbanisation, increasing travel and population growth, which makes it easier for diseases to spread rapidly and is also increasing human exposure to zoonotic disease reservoirs as cities expand into more rural areas. Globalisation and increased population movement is also enabling diseases to spread further and faster. There are unpredictable disease outbreaks from new pathogens or ones for which no current vaccine exists (such as Zika), and more predictable outbreaks of vaccine preventable diseases (VPD) for which Gavi provides support through stockpiles or routine immunisation. The latter are exacerbated by low immunisation coverage, weak country capacity for surveillance and disease diagnosis, and a focus on outbreak response instead of prevention. Disease outbreaks can be hugely disruptive as they usually require an intense response effort, diverting health care workers away from routine immunisation. In more serious cases, outbreaks can also cause broader economic and social disruption, interrupt provision of health and immunisation services and significantly undermine confidence in the health system (including potentially in the effectiveness of vaccines). This impact can also spread to neighbouring countries and beyond as other countries manage the potential or actual spread of the disease.

Through its HSS grants, Gavi support contributes to long-term efforts to increase the resilience of health systems and routine immunisation programmes, helping to make them more capable of withstanding, detecting (through robust disease surveillance) and responding to disease outbreaks (including through immunisation campaigns, social mobilisation and contact tracing). Disease surveillance is a key area for the Data Strategic Focus Area. Gavi also provides vaccine support for many diseases with outbreak potential including measles, meningitis, cholera, yellow fever, typhoid, and polio. For many of these diseases, Gavi supports multiple elements of disease control including routine immunisation, preventive campaigns and outbreak response (including vaccine stockpiles). The Fragility, Emergencies and Refugees policy provides flexibilities to conduct preventive immunisation for refugees. The Alliance also signed an advance purchase commitment to accelerate availability of Ebola vaccine (which was instrumental in containing the Ebola outbreaks in the Democratic Republic of Congo this year) and other vaccines for outbreak response are currently being explored as part of the new Vaccine Investment Strategy. Through the Coalition for Epidemic Preparedness Innovations (CEPI) the availability of vaccines to prevent or respond to outbreaks may also increase in the future.

Current exposure to this risk is high as Gavi-eligible countries remain particularly vulnerable to outbreaks since they are home to reservoirs for many diseases and often have weak public health capacity to prevent, detect and respond to them. Gavi continues to ensure that countries at-risk from VPD outbreaks introduce the vaccine, and continues to emphasise the importance of preventing, rather than responding to, outbreaks with in-country coordinating bodies and partners. However, fully addressing the significant gaps in Gavi-eligible countries' health systems and critical public health capacities, particularly in a short time-frame, would require



engagement beyond Gavi's current mission and resources (although a stronger role in global health security is considered as a potential direction for Gavi 5.0, and this Board will discuss support for Yellow Fever surveillance). Furthermore, outbreaks due to new pathogens are beyond Gavi's capabilities to anticipate or intervene. The Alliance therefore accepts that there is significant risk that outbreaks may continue to impact routine immunisation, and current exposure is therefore within its risk appetite. The Alliance has a lower appetite for the risk of outbreaks of diseases for which Gavi provides vaccine support and for outbreaks having a sustained adverse impact on routine immunisation coverage after the outbreak is over.

## g) Misuse by countries

### *Deliberate misuse of Gavi support in some Gavi-supported countries*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
g Misuse by countries Deliberate misuse of Gavi support in many Gavi-supported countries	<ul style="list-style-type: none"> <li>• Culture of gifts/corruption</li> <li>• Opportunity for personal gain</li> <li>• Weak monitoring/deterrence</li> <li>• Weak institutions / systems</li> </ul>			SOMEWHAT OUTSIDE		

Gavi uses country supply chains for vaccines and seeks to channel funds through country systems whenever possible, in order to ensure country ownership of programmes and to build the sustainable capacity of countries to manage those programmes, which is critical for development especially as countries approach transition. However, as the Alliance works with the poorest countries in the world, many have weak systems, low capacity, poor governance and management, and / or prevailing corruption, and this exposes the Alliance to the risk of its support being misused (deliberately as well as by mistake). The inherent risk is particularly high for cash support programmes which account for 20-25% of Gavi's programmatic expenditure – the remainder being vaccines procured through UNICEF. Vaccines are less prone to theft and diversion, due to a lack of secondary markets. Inherent exposure is increasing – both due to the increase in the value of cash grants (which are forecast to reach US\$ 1.3 billion 2016-2020) and the increasing concentration of those grants in countries with weaker systems (as stronger countries transition). Misuse can have a financial cost to Gavi if not reimbursed and it reduces the impact of its investments. It can result in the suspension of cash support to countries, undermining their programmes, and create significant transaction costs to manage that support and address fiduciary risks. Significant or sustained cases of misuse can impact the reputation of the Alliance, potentially undermining donor and Board confidence. Misuse can also be an indicator of weak overall systems which may impede countries' ability to effectively manage their programmes and successfully transition out of Gavi support.

To manage this risk, the Secretariat has strengthened grant oversight by Senior Country Managers and budget, expenditure and financial reporting reviews by a specialist Programme Finance team. Furthermore, before a new grant starts, Programme Capacity Assessments (PCAs) assess a country's capacity to manage support and, together with other intelligence (internal knowledge of the country context and risks, internal and external audit reports, and external assessments if available), these inform Gavi's grant management requirements (GMRs) and fiduciary measures. When government systems are insufficiently robust, Gavi can require strengthening measures to ensure strong fiduciary oversight. These can be conditional to disbursement and / or to be addressed during implementation. It can also decide to channel funds through alternative channels (e.g., partners) while continuing to strengthen country systems so the Alliance can revert to using them. As GMRs are implemented by countries and tracked by SCMs, the PCA team will carry out follow-up Monitoring Reviews to assess progress and whether, in cases where funds had been channelled away from government systems, national systems are now robust enough to meet fiduciary requirements. In an increasing number of countries, a 'hybrid' approach is adopted, whereby several financing channels and modalities are used to mitigate risk, while continuing to help strengthen national systems. Furthermore, Programme Audits are conducted periodically with higher risk programmes being covered more frequently. Gavi has also set up

an anonymous and confidential whistle-blower hotline to which anyone can report suspected misuse, and has a dedicated fraud investigator to follow up on any suspected cases.

Current exposure to this risk is high, mostly in terms of likelihood given the inherent risk in Gavi-supported countries, but less in terms of potential impact, given that due to its zero tolerance of misuse, Gavi has to date received close to 100% payments against scheduled reimbursement for misuse found by Programme Audits. However, these audits have identified persistent financial management weaknesses in many of the Gavi supported countries, ranging from unsupported expenditure and weak controls to deliberately misused funds. To some extent these are symptoms of the light-touch approach of the past (as audits are retrospective), and identification of these weaknesses should help strengthen country systems and fiduciary oversight – and therefore reduce residual risk going forward. However, while significant enhancements in fiduciary measures have been implemented, it also has become clear that there are limitations to Gavi's current approach to managing fiduciary risks, including channelling funds through Alliance partners in many countries. Gavi will need to further explore and test other approaches that can provide strong and transparent monitoring and assurance in countries, while also using and building country capacity (this will be further discussed in the Risk Management item at this Board).

Current risk exposure is therefore still somewhat outside risk appetite. The Alliance has a preference to channel support through government systems when these are sufficiently robust and acknowledges this comes with inherent risks. However, the Alliance has a low appetite for the risk of deliberate fraudulent misuse occurring, or for any form of misuse occurring at scale. When government systems are insufficiently robust, alternative mechanisms need to be used to ensure strong fiduciary oversight.

## h) Donor support

### *Significant reduction in donor support to Gavi*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
h Donor support Significant reduction in donor support to Gavi	<ul style="list-style-type: none"> <li>Reduction in development budgets</li> <li>Competing priorities in development</li> <li>Competing priorities within health</li> <li>Loss of donor confidence in Gavi</li> </ul>			SOMEWHAT OUTSIDE		

Donor support is crucial to enable Gavi to sustain approved programmes and fund new programmes. However, continued economic uncertainty, shifting political ideologies, increasingly hostile media in some countries, and competing priorities in development and health (such as refugees, security, climate, and education, but also the creation of other health initiatives) may lead to a reduction in future donor support to Gavi. Elections in key donor markets can bring new leaders that take different directions from their predecessors and need to respond to a growing segment of discontented voters with increasing mistrust of established institutions. Reduced budget for Gavi programmes could lead to disruption of countries' immunisation programmes and reduced health impact. It could also prevent the Board from opening support windows for new vaccines that are developed. Reduced donor support would likely also increase the effort and cost of mobilising resources and servicing donors.

Gavi has been working to diversify its donor base and its support is less concentrated from a few large donors than in the past. The Secretariat, and especially the resource mobilisation team, invest significant efforts in engaging donors and ensuring their needs are met, including with financial instruments tailored to donors' budgetary processes and requirements. Gavi engages with numerous multilateral reviews and evaluations, and the Mid-Term Review at the end of this year is another opportunity to showcase results and the effectiveness of Gavi's model. Gavi also works to increase the Alliance's profile (through communications and advocacy organisations) in donor countries. There is a particular focus on key markets experiencing political

and economic uncertainties with tailored strategies including bipartisan engagement, proactive outreach to political leadership and the creation of an expansive network of supporters in civil society and media, as well as private sector champions in key markets. More broadly, the Secretariat is working to increase private sector engagement in the Alliance and to leverage private sector investment, expertise and innovation.

This risk remains high mostly due to its potential impact. Recent elections in key donor countries are reminders of continued anti-establishment, anti-globalisation and anti-immigrant sentiment in many countries. Gavi also lost many champions due to electoral changes and is having to rebuild high-level champions. This uncertainty is exacerbated by recent foreign exchange fluctuations between donor currencies and the US dollar (in which most Gavi expenditure is denominated) as well as uncertainty over the implications of the planned exit of the UK from the European Union in March 2019. As this mainly affects traditional markets, an ongoing focus on engaging newer donors remains therefore important. Multiple competing replenishments will take place in the health and development sector before Gavi's replenishment in 2020. The fact that the Board includes key donors and other stakeholders in global development helps to ensure Gavi's continued relevance to donor priorities. In addition, the current strategy development process leading up to the Board's approval of the next strategy in 2019 ensures continued relevance and a unique value proposition for the next replenishment in 2020.

The Alliance has a low appetite for risks affecting the sustainability of donor funding in order to safeguard predictable financing of vaccines, as this is crucial to sustaining Gavi's existing programmes and the Alliance's ability to fund new vaccines. The current exposure is low in terms of likelihood but high in terms of potential impact, so is still somewhat outside risk appetite and requires ongoing attention, especially as Gavi approaches replenishment in 2020.

## i) Polio transition

*Loss of immunisation-critical public health capacity in Gavi countries due to the winding-down of polio eradication operations*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<b>I Polio transition</b> Loss of immunisation-critical public health capacity in Gavi countries due to the winding-down of polio eradication operations	<ul style="list-style-type: none"> <li>• Large reliance on GPEI-funded staff and assets</li> <li>• Weak national systems</li> <li>• Delayed transition plans</li> <li>• Incomplete polio asset mapping</li> </ul>			<b>SOMEWHAT OUTSIDE</b>	<b>NEW</b>	

Over the last three decades, the Global Polio Eradication Initiative (GPEI) has built infrastructure for disease surveillance, social mobilisation, and vaccine delivery with the goal to eradicate polio worldwide. In many countries, especially those that have already eliminated polio, this infrastructure is also used beyond polio eradication, supporting routine immunisation, measles campaigns, maternal and child health programmes, disease surveillance, and outbreak response. GPEI has also pioneered capabilities and tools such as micro-planning, programme management and population tracking, which could be beneficial if mainstreamed into routine immunisation programmes. With eradication coming closer, GPEI is gearing up to develop a strategic plan to achieve the certification of polio eradication, after which it will sunset (although it is currently not yet clear when this will happen given there remain endemic countries). With that will likely come a ramp down of its financial support for activities in countries that have eliminated polio, and GPEI has therefore initiated planning with countries to map polio assets and determine the functions that can be repurposed to support broader health goals.

While some GPEI-funded staff and assets, particularly those related specifically to conducting oral polio vaccine mass campaigns, can be let go with likely minimal impact on broader immunisation programmes, the loss of others, particularly related to disease surveillance, outbreak response and programme management,

could have a larger impact on immunisation programmes. If the transition of immunisation-critical assets is not well-managed, public health capacity may be lost in some countries that would adversely impact national immunisation programmes including efforts to improve coverage and equity and conduct high-quality campaigns. Polio transition may also adversely impact WHO's capacity to support countries, particularly in sub-Saharan Africa, where its country offices and programmes are highly dependent on polio staff and funding.

In order to understand the contribution of polio assets to routine immunisation programmes and to determine where gaps will arise if those activities cease (or where this presents an opportunity to strengthen routine immunisation by repurposing assets), polio asset mapping exercises are being undertaken by countries facilitated by GPEI. As more detailed asset mapping becomes available, Gavi's annual Joint Appraisals are including this information in country discussions to understand risks and opportunities to immunisation programmes associated with polio budget decreases and prioritise the functions they wish to maintain. Through HSIS and PEF TCA, Gavi can provide time-limited bridge-funding support to countries to mainstream key functional areas of polio into routine immunisation programmes. However, progress to ensure full country ownership of polio transition planning is mixed without many finalised plans with detailed budgets and potential funding sources for assets to be maintained. GPEI is under considerable financial pressure due to the difficulties of eliminating polio from the last three polio-endemic countries, Afghanistan, Pakistan, and Nigeria, so it may need to accelerate its reductions in support for work in countries that have eliminated polio.

Gavi's current exposure to this risk varies by country but is overall high. It exists particularly in a small number of fragile countries where the footprint of GPEI is relatively large and national systems are very weak. Chad, Somalia and South Sudan have been assessed as very high risk, and DRC, Ethiopia and Sudan as high risk. At present, the three endemic countries (Afghanistan, Nigeria and Pakistan) will have their GPEI funding maintained beyond 2019, so assets are not at immediate risk. In most other countries, routine immunisation programmes are less reliant on polio assets, but polio transition may impact specific capacities, particularly in disease surveillance. There continues to be a need to obtain more granular information to help validate the activities affected by polio transition, including understanding what activities polio staff are currently undertaking and identifying skilled polio personnel to be repurposed to fully support routine immunisation. WHO has already intensified efforts to do asset mapping and understand better, country by country, the extent that polio assets might be contributing to routine immunisation, as well as developing a roadmap to maintain surveillance, the flagship of the GPEI polio eradication.

The Alliance has a low appetite for the risk that loss of immunisation-critical assets may affect routine immunisation in the weakest countries. As current exposure varies by country it is overall somewhat outside risk appetite (with the six countries identified most at risk more clearly outside), but expected to decrease going forward, given actions being undertaken by WHO. The Secretariat is also more proactively engaging with countries and partners to support transition planning and incorporate aspects of polio transition into Joint Appraisals and other planning activities. While Gavi can provide time-limited bridge-funding support to these countries to mainstream key functional areas of polio into routine immunisation programmes, it is essential that country demand for these assets exists and full country ownership for polio transition planning is guaranteed, including a clear transition plan with milestones and funding sources post bridge-funding identified.

## j) IT disruption

### *Critical information systems or data significantly compromised by cyber-attack or technology failure*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
j) <b>IT disruption</b> Critical information systems or data significantly compromised by cyber-attack or technology failure	<ul style="list-style-type: none"> <li>• Cyber-attack, phishing and malware</li> <li>• Internal or external data breach</li> <li>• Systems failure and data loss</li> </ul>			<b>SOMEWHAT OUTSIDE</b>	<b>NEW</b>	

The Secretariat continues investing in its knowledge management and information systems aimed at enhancing Secretariat processes (especially with regard to grant management and financial management) and enabling better engagement with countries and partners. The increasing use of automated systems and centralised cloud-based data repositories to support collaboration and maximise work efficiency mitigates risks related to human error and process delays, but the increasing reliance on technology also exposes the Secretariat to technology-related risks. A significant IT systems failure, data loss or sensitive data breach could happen due to cyber-attacks, internal or external data leaks, technology glitches, or new system implementation challenges. This could interrupt the Alliance's operations for a prolonged period of time, e.g. due to an inability to maintain communications and coordination internally and externally, an inability to complete disbursements to countries, partners or employees, or an inability to approve, manage, and monitor grants. It could also result in financial fraud or exploitation. Beyond its direct impact, it can lead to reputational impact and erode stakeholder trust.

The Secretariat has implemented several measures which include internet traffic monitoring and filtering, single sign-on with multi-factor authentication, application security testing and annual security scans. The Secretariat is furthermore implementing a Security Operations Center and system event analytics in collaboration with the Global Fund. Digital security training and awareness sessions are also being planned. Gavi's cloud-based systems provide a level of redundancy and back-up across key systems. In addition, the Secretariat has implemented an independent back-up solution which provides the ability to restore key data at a transactional level. A next step will be to identify independent hosting arrangements where data could be restored in the event of a catastrophic failure of a cloud-based system. Gavi is also implementing a comprehensive business continuity and disaster recovery plan which will include testing and verification of system recovery.

The external threat is high with cyber-attacks, including ransomware, phishing and malware, continuing to increase globally. In the same time the Secretariat is increasingly relying on technology, including plans for a large-scale implementation of new financial and grant management systems. Recent internal audits have found further opportunities for improvement in policies and practices, including strengthening disaster recovery processes and technical capabilities along with increasing the maturity of cyber-security technologies and approaches. With the move to the Global Health Campus finalised, these are now being addressed. Until the audit recommendations are fully implemented, current exposure to the risk of IT disruption remains high and somewhat outside risk appetite. The Alliance has a low appetite for the risk of critical information systems or data being compromised, since these are critical to coordinate the Alliance. The Secretariat seeks to maintain robust processes and management, and reliable and secure systems, to prevent interruption of core systems and business-critical operations.

## k) Strategic relevance

### *Gavi becomes less relevant to global development priorities*

	Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
k	Strategic relevance Gavi becomes less relevant to global development priorities	<ul style="list-style-type: none"> <li>• Prioritisation of other development causes</li> <li>• Inability to remain innovative and adapt</li> <li>• Reduced faith in Gavi's capacity to deliver</li> <li>• Growing portion of unmet immunisation needs outside Gavi countries</li> </ul>			SOMEWHAT OUTSIDE		

Gavi was launched on the eve of the Millennium Development Goal era as a critical new mechanism for achieving the third MDG. Both its mission and its model were highly relevant to global efforts to reduce child mortality and eradicate poverty, and it has continued to evolve its model and policies to reflect new geopolitical trends and priorities. This has been critical to the ability of the Alliance to mobilise resources, engage at the highest political levels with countries and ensure immunisation remains prominent on the international agenda. However, as the world enters the Sustainable Development Goal (SDG) era, there is a risk that immunisation and Gavi become less relevant. There is less global focus on health as a holistic sectoral goal and as an enabler for development. There are also a number of other competing priorities in development (such as refugees, security, climate, and education) and health (e.g., non-communicable diseases, nutrition). More players are entering an increasingly complex and fragmented global health landscape and there is a risk that progress on immunisation is seen as largely complete given high coverage of basic vaccines (which now reach 86% of children globally). Moreover, Gavi's geographic scope will become increasingly limited as countries transition, and under current policies 70% of under-immunised children globally (based on children receiving three doses of DTP-containing vaccines) will live in countries that are not Gavi-eligible by the middle of the next strategy period. This may lead to reduced funding and political commitment for immunisation globally, and in the remaining Gavi countries specifically.

To address this risk, Gavi periodically reviews its policies to ensure they are adapted to global priorities. Continuous efforts are made to increase Gavi's public profile (through communications, advocacy organisations, champions and ambassadors for immunisation). Gavi is also engaging in relevant policy fora to advocate for ambitious goals (two SDG3 indicators have been adopted related to immunisation (3.b.1, 3.8.1), and Gavi is engaged in the Global SDG3 Action Plan) and highlight the relevance of vaccines to other priorities (e.g., universal health coverage, global health security, anti-microbial resistance). The fact that the composition of the Board includes key stakeholders in global development helps to ensure continued relevance of Gavi in line with global development priorities. Gavi is also working to better coordinate with other health actors (e.g., the Global Fund and the Global Financing Facility (GFF)). The Board also has indicated a desire to ensure the Gavi "platform" to shape markets, accelerate adoption of new technologies (including new vaccines against priority diseases) and advocate for immunisation, remains available to a broader set of countries, even as many transition out of financial support. Finally, Gavi's strategy development process (with an initial discussion during the past Board Retreat and further discussions during this Board) leading up to the Board's approval of the next strategy in 2019, is an important mechanism to demonstrate continued relevance of Gavi's unique model, mission and goals in the context of the SDGs and current global development priorities such as global health security.

Current exposure to this risk remains high, mostly in terms of potential impact. The Alliance has a low appetite for the risk that it becomes less relevant to global development priorities and this is currently still somewhat outside appetite. However, the ongoing and upcoming discussions on Gavi 5.0 will be defining for the further evolution of this risk. As further discussed in the Gavi 5.0 paper, even if Gavi's mission and strategic goals would remain relevant, *how* it will achieve this may require changes for it to remain relevant and effective (e.g. more targeted and differentiated programmatic approaches, and funding and operating models that better adapt to country situations and needs).

## I) Frequent or unplanned campaigns

*Frequent or unplanned mass vaccination campaigns undermine capacity of governments to manage routine health and immunisation services*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<b>I</b> Frequent or unplanned campaigns Frequent or unplanned mass vaccination campaigns undermine capacity of governments to manage routine health and immunisation services	<ul style="list-style-type: none"> <li>Periodic very large cash inflows for campaigns</li> <li>Front line workers diverted to implement campaigns</li> <li>Management capacity diverted to manage campaigns</li> <li>Infrastructure (e.g., supply chain, transport) repurposed for campaigns</li> <li>Poor planning and management undermine quality of the campaign, resulting in low coverage</li> </ul>			<b>OUTSIDE</b>		

In Gavi's current strategic period, campaigns account for a higher proportion of Gavi supported activities than in the previous period, reflecting Gavi's stronger engagement in epidemic and accelerated disease control initiatives. By immunising a large target population in a short period of time, campaigns supplementary to routine immunisation (also known as supplementary immunisation activities (SIAs)) help to rapidly increase population immunity and are thus an important tool for both preventing and responding to disease outbreaks. At the same time, frequent or unplanned mass vaccination campaigns can disrupt routine immunisation programmes and health systems by diverting health workers and resources away from routine services, potentially incentivised by providing financial "per diems" for participating in campaigns. This can undermine routine immunisation, especially when repeated campaigns occur in a short period. The quality of implementation can vary significantly and some countries have to frequently repeat campaigns due to a failure to achieve sufficient coverage among the target population. They are also expensive (with per diems for training, supervision, service delivery, and transport typically a major cost driver), resulting in large sums of money being disbursed in a short period of time, increasing the risk of misuse. Some countries rely heavily on campaigns, often to compensate for poor routine immunisation coverage. While justified under certain circumstances, such reliance on campaigns is not sustainable given their cost and disruptive impact. Nonetheless, well-planned targeted campaigns, as part of a comprehensive immunisation delivery strategy, remain valuable and necessary to raise the profile of immunisation, vaccinate missed children, and mitigate risks of outbreaks. All members of the Alliance are expected to work with countries to ensure that campaigns are planned and executed in a manner that protects – and ideally strengthens – the broader immunisation programme.

The Secretariat has been increasing efforts to improve the quality of campaigns with Alliance partners through more careful planning, systematic readiness assessments, and by promoting country-tailored strategies that reinforce routine delivery (e.g., Periodic Intensification of Routine Immunization (PIRI)) and multiple interventions in one campaign. WHO has set up a working group to update PIRI guidance, and countries are starting to include PIRIs in their HSIS proposals. The health system and immunisation strengthening (HSIS) framework requires all countries to articulate how they will use operational cost support for campaigns to strengthen their routine immunisation programmes and health systems, and encourages countries to invest operational grants in longer-term health systems strengthening. The Alliance also requires that all campaigns include a coverage survey to evaluate the quality of implementation and identify unreached populations (for more targeted follow-up campaigns). The Secretariat is also reviewing campaign budgets before disbursing funds to minimise perverse incentives and misuse.





However, current exposure to this risk has further increased, given the growing number of countries conducting periodic campaigns. Among 12 Gavi supported countries conducting nationwide measles and/or rubella SIAs in 2017, only one (possibly two) achieved the 95% coverage target as determined by a post-campaign coverage survey. Furthermore, The Strategic Advisory Group of Experts on Immunization (SAGE) reports that for all SIAs in 2017 in less than half were coverage rates in excess of 95% achieved. This highlights continued challenges with planning and conducting high quality campaigns, which has the potential to disrupt routine

immunisation services. MCV1 coverage in the Gavi 68 countries has remained unchanged at 78% during 2015-2017, and with MCV1 coverage determining the frequency of campaigns, several countries appear to be stuck in a cycle of low routine immunisation coverage and repeated vaccination campaigns with inadequate coverage. This Board will therefore discuss a proposal for how to better balance incentives for Gavi supported measles and rubella immunisation activities. In parallel, WHO and SAGE guidance is necessary to break the cycle of periodic nationwide SIAs.

The increased exposure is now outside risk appetite. The Alliance has a low appetite for the risk of immunisation campaigns undermining the effectiveness or sustainability of routine immunisation – although risk appetite is somewhat higher in the case of emergency campaigns responding to disease outbreaks. Continued reliance on campaigns undermines the goal of strengthening health systems and durably improving population coverage.

### m) Partner capacity

*Sum of comparative advantages of Alliance partners is inadequate to effectively deliver required technical support to countries*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
m Partner capacity Sum of comparative advantages of Alliance partners is inadequate to effectively deliver required technical support to countries	<ul style="list-style-type: none"> <li>Lack of alignment and coordination</li> <li>Lack of capacity / expertise</li> <li>Lack of availability</li> </ul>			BROADLY WITHIN		

Alliance core and expanded partners play a critical role in the Alliance's ability to deliver on its mission and strategy, including by setting norms and standards in immunisation, procuring vaccines, providing technical information for Gavi policies and strategies, and providing technical and capacity-building support to countries to strengthen their immunisation programmes. Partners' collective capacity to provide the full range of support which countries require is therefore critical. The ambitious goals of the Alliance's 2016-20 strategy require new and intensified support to countries including assistance in areas that go beyond the traditional comparative advantages of partners. It also requires that the support is truly country-owned and better coordinated across partners.

To address this risk, the Partners' Engagement Framework (PEF) model has focussed on delivering more partner capacity directly to countries (with now over 200 PEF funded staff providing technical assistance at country level), and further enhanced the effectiveness, efficiency and transparency of collaboration with core partners. Following the evaluation of Alliance technical assistance to countries (which found that TA funded by Gavi was not clearly laying out whether it was for short-term gap-filling instead of for transfer of knowledge and sustainable capacity building), 2018 TA guidance now includes a specific section on 'Transfer of skills' detailing the objective and approach for it, and the PEF Management Team oversees TA delivery in 20 priority countries with continued attention to lessons learned based on independent reviews. Core partners (WHO, UNICEF, World Bank and CDC) remain the prime recipients of PEF funding, with WHO and UNICEF receiving 79% of core funding. However, in 2017, 43 expanded partners (including local institutions in Mauritania, Pakistan, Kenya and Senegal) and 30 private sector partners were engaged, bringing new areas of comparative advantage.





The current risk exposure has therefore decreased and is now brought within risk appetite. Countries are aligning a mix of partners to achieve results based on the partners' respective areas of expertise. For example, in DRC, a mix of core and expanded partners (including civil society organisations) are engaged to drive progress on data, supply chain and demand generation. Gavi is continuing to empower countries to assess their technical assistance needs and the quality of technical assistance provided, as well as expanding the



pool of providers including local institutions, where appropriate. The Alliance has a low appetite for this risk, since partner capacity is critical to delivering on its mission and strategy.

## n) Global supply shortages

### *Shortages in the global vaccine supply affect Gavi-supported countries*

	Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
n	Global supply shortages Shortages in the global vaccine supply affect Gavi-supported countries	<ul style="list-style-type: none"> <li>Manufacturing capacity inadequate to meet demand</li> <li>Unable to meet country presentation preference</li> <li>Lack of supply security</li> <li>External disruption</li> </ul>			SOMEWHAT OUTSIDE		

Secure and reliable vaccine supply is essential for immunisation programmes to run uninterrupted, to enable new vaccine introductions, and to meet countries' vaccine presentation preferences. However, vaccine production is a technically challenging process and there are only a limited number of vaccine manufacturers for many of the Gavi-supported vaccines. Other factors are the total production buffer capacity for each market, manufacturers' engagement with global health and development aid, their assessment of commercial risks associated with investments, market entry barriers, and the strength of National Regulatory Authorities (NRAs). Country demand may also delay or surge depending on country introduction readiness and disease outbreaks, conflict and natural disasters, while the production of vaccines and increasing production capacity is a long-term process. There is also natural volatility in demand, especially for newer vaccines and those with more sporadic use (e.g. with vaccines delivered for campaigns). The risk of supply shortages is generally decreasing for Gavi's more mature routine vaccine programmes (e.g., pentavalent and PCV) as supply capacity has increased over time and demand is more stable owing to more predictable usage patterns in countries where immunisation programmes are established. However, it remains a high risk for a number of vaccines and the inherent risk may grow if Gavi decides to support additional new vaccines in the future, especially for epidemic diseases. Also as countries transition out from Gavi support they may opt for self-procurement instead of procuring through UNICEF. Reduced pooled demand may impact Gavi's ability to influence manufacturer production, scale-up, and R&D investment decisions.

One of the key objectives of the Alliance's Supply and Procurement Strategy is to ensure sufficient and uninterrupted supply of appropriate and affordable vaccines. The Secretariat and Alliance partners work closely with industry to improve the health of vaccine markets, which may entail incentivising increased production capacity to meet demand, through provision of long-term demand forecasts and other strategic information and incentives. This can involve encouraging existing manufacturers to expand capacity or new ones to enter the market. Annual base demand forecasts are updated to project demand for the next 10 years. Strategic demand scenarios are also developed based on strategic needs to model demand variation based on key strategic assumptions. The Alliance secures required supply through long-term agreements with manufacturers, and ensures quality-assured vaccines through the WHO prequalification process, which also supports regulatory capacity-building of local NRAs and facilitates international harmonisation of vaccine production standards. Secretariat and Alliance partners furthermore engage countries to understand needs and product preferences, introduction preparedness, and shares information to facilitate country planning, budgeting, and decision making. Vaccine stockpiles are created for outbreak preparedness for epidemic diseases in case emergency response is needed after an unpredicted outbreak.

Current exposure remains high but stable on a global portfolio level, with the number of healthy vaccine markets increasing (three vaccine markets currently have moderate or high levels of healthy market dynamics: Pentavalent, Yellow Fever, and PCV). Supply security has improved significantly for the YF market (despite significant outbreaks in Brazil and Nigeria, which drew on the global yellow fever vaccine stockpile), due to manufacturer investments supported by the Alliance, particularly on demand forecasting and supply planning.

In the absence of major YF outbreaks, this should provide enough supply to meet demand for routine vaccination and mass campaigns and also to maintain the global stockpile. However ongoing supply challenges for IPV and HPV are holding back new introductions and require a revision of targets. In the last two months, the Secretariat was informed of new supply constraints for Rotavirus vaccine. The preferred manufacturer has faced technical challenges which have impacted their production, which will delay new introductions in 2018 and 2019. The other manufacturer is reducing the volume they are supplying to the Gavi market, which has already resulted in stock-outs in some countries. All affected countries are being supported to consider switching to newly prequalified products from two Indian manufacturers. This illustrates that this risk continues to be high and requires to be monitored closely. The Alliance is in frequent contact with relevant manufacturers to minimise the impact on active programmes and future introductions.

The overall risk exposure is currently somewhat outside appetite. The Alliance has a moderately low appetite for the risk of supply shortages, especially if this may impact existing programmes. While ensuring sufficient and uninterrupted supply of vaccines is essential, it is also acknowledged that demand and supply are inherently volatile. Future supply security is dependent on assumptions of supplier production capacity scale-ups and new market entrants that introduce sufficient buffer capacity and supplier diversity into the markets. Also, mitigation is constrained by limitations in degree of impact on supplier actions and manufacturers' own limitations in addressing technical challenges. Current market assessments identified future market health risks that may limit progress to moderate healthy market dynamics. For example, timely entry of pipeline IPV and MR products will be required to improve healthy market dynamics, yet there is moderate risk of delays to market entry.

### o) HSIS value for money

*HSIS investments do not materially improve programmatic outcomes*

Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
<p>o HSIS value for money HSIS investments do not materially improve programmatic outcomes</p>	<ul style="list-style-type: none"> <li>Key bottlenecks not addressable by HSIS</li> <li>HSIS grants not designed to target key bottlenecks</li> <li>HSIS grants duplicative with other donor funding</li> <li>HSIS grants not large enough to have significant impact</li> <li>HSIS not disbursed in timely fashion</li> <li>Programmes funded by HSIS not well-managed</li> <li>Misuse of HSIS resources</li> </ul>			<b>BROADLY WITHIN</b>		

HSIS grants are one of the key financing tools for the Alliance to help strengthen coverage and equity and build sustainability in immunisation programmes, and are therefore critical to delivering the Gavi strategy. HSIS includes grants for health system strengthening, vaccine introductions and operational support for campaigns. The Alliance is projected to invest nearly US\$ 2 billion in HSIS between 2016 and 2020, including US\$ 1.3 billion in health system strengthening grants. Nonetheless, Gavi's HSIS support is intended to be catalytic and covers only a small proportion of the total financing required to implement sustainable programmes with high and equitable coverage, and the largest financing typically comes from governments. Some of the key barriers to coverage and equity may not be addressable through HSIS grants (e.g., design of the overall health system). Moreover, the impact of HSIS grants depends on them being well-designed, focused on the key bottlenecks, and well-spent. Even when HSS grants are well-used, many factors are impacting the performance of immunisation programmes so Gavi can contribute but not fully attribute its investments to outcomes and impact. Without robust management and oversight – including aligned technical support where required from Alliance partners – HSIS funds could remain unspent, be channelled to low impact investments or misused. The inherent risk is likely to increase as stronger countries transition out of Gavi support and Gavi's grant portfolio is more concentrated in countries with weaker systems.

Gavi has continued to strengthen its processes for the design, monitoring and improvement of grants. The HSIS framework, approved by the Board in 2016, was designed to improve the design of HSIS grants and

ensure greater alignment between HSS, vaccine introduction and operational support grants. The Joint Appraisals – annual reviews by all in-country stakeholders - have now become a valuable part of the annual EPI cycle in most countries, and are strengthening linkages between Gavi HSS, NVS and PEF grants. The Partners' Engagement Framework (PEF) has helped ensure that technical support is based on country needs, better connected to Gavi's other grants and has increased the transparency and accountability of partner support. Grant performance frameworks are used to monitor and assess the performance of HSS grants. As part of the annual cycle of review and monitoring of grants, there is a deliberate discussion on identifying technical support priorities for the next year, and consideration of whether adjustments are needed to ensure that grants are optimally targeted towards coverage and equity. This has also enabled countries to accelerate implementation of grants in countries that have experienced challenges in absorbing HSS funding. All HSIS grants now have robust performance frameworks with intermediate indicators measuring direct outputs as well as outcomes and help the Alliance course correct as required. As of 2017, 14 countries have included sub-national indicators in their GPF specific to their HSS grant support.

Current risk exposure is high, but broadly within risk appetite. To achieve its coverage and equity aspirations, the Alliance has to be ambitious and explore innovative strategies to strengthen health systems and immunisation programmes. It therefore has a moderately high appetite – where required – for the risk that HSIS investments do not substantially improve outcomes as long as there is robust design, implementation and oversight of HSIS grants.

## p) Forecasting variability

### *Gavi forecasting variability driving inappropriate decision-making*

	Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
p	Forecasting variability Gavi forecasting variability driving inappropriate decision-making	<ul style="list-style-type: none"> <li>• Uncertainty over vaccine demand</li> <li>• Financial uncertainties (e.g., prices, FX)</li> <li>• Complexity of process</li> <li>• Sub-optimal systems</li> </ul>			<b>BROADLY WITHIN</b>		

The Secretariat develops forecasts of future country demand, vaccine supply and pricing, and financial expenditure to inform annual procurement of vaccine doses and funding decisions. These also inform the Alliance's impact projections as well as key policy and strategy decisions (e.g., vaccine investment strategy). Forecasts are based on a number of inputs and assumptions including on vaccine demand (projected vaccine introduction dates and uptake, estimates of target population and immunisation coverage in each country, wastage estimates depending on product presentations, and countries' projected Gross National Income (GNI) defining their co-financing share and transition date); on vaccine pricing (market dynamics, pipeline assumptions, and exchange rates); on vaccine supply (manufacturing capacity); on cash disbursements (country absorptive capacity, fiduciary risk conditions) and vaccine disbursement timing; on Partner and Secretariat operating costs; on resource inflows (donor contributions, innovative financing proceeds, and investment income); and on potential Gavi policy changes. Each of these has inherent uncertainties and, in some cases (e.g., for population and coverage estimates in some countries), challenges with data quality.

Gavi's forecasts inform planning decisions by a range of stakeholders including countries (who plan introductions based on their understanding of availability of Gavi funding and vaccine supply), donors (demand and impact forecasts inform their decisions on the size and timing of their pledges), manufacturers (who use Gavi forecasts to plan their production schedules) and the Secretariat and Alliance partners (who use them for financial, strategic and operational planning). Significant deviation from forecasts could therefore result in Gavi having inadequate financial resources to fund country demand (or conversely being perceived to have "excess" funding), countries having to delay introductions (or conversely have excess supply potentially leading to

wastage), and manufacturers producing inadequate or excess volumes of vaccine. It may also result in Gavi failing to deliver on its targets if these turn out to be overly aggressive.





To mitigate this risk, the Secretariat has been strengthening its forecasting processes and workflows with more systematic collaboration across key teams responsible for vaccine supply, market shaping, co-financing and transition, and finance – informed by and validated with Alliance partners. Checks and balances are built in to the process and data is reviewed and triangulated with other sources, e.g. shipment history and stock and coverage levels. Key assumptions are pressure tested and variance drivers communicated. Financial forecasting updates are regularly provided to senior management, the Audit & Finance Committee (AFC) and the Board with transparency on the key drivers of change between forecast versions. Potential financial impact is further mitigated with a cash and investments reserve, equivalent to eight months' future expenditure at least, and a surplus for expected future requests for programme funding.

Current risk exposure is limited for the overall long-term financial forecast (with current accuracy of financial forecast for programmatic expenditures within our target of 10% variance), but inherent variability and uncertainty is higher in programmatic forecasts. Forecasting of the mature and routine vaccine portfolio (pentavalent, pneumococcal and rotavirus) has improved with variances in projected expenditure due largely to reductions in pricing and better management of vaccine stocks. However, risk exposure remains high for newer vaccine programmes and those that are delivered through campaigns. The timing and size of country demand, as well as the availability of supply, is harder to forecast for these programmes (and changes in demand impact both vaccine support and HSIS support due to the knock-on effect on vaccine introduction grants or operational cost support).

Overall, this exposure is broadly within risk appetite and can be effectively managed through existing processes. The Alliance has a higher appetite for the risk of forecasts being too high – to ensure availability of sufficient supply and funding – than for forecasts being too low and recent forecasts have been consistent with this. It has a lower appetite for the risk that such variability might reduce manufacturer or donor confidence and therefore seeks to actively and regularly communicate the assumptions, uncertainties and changes in its forecasts.

## q) Secretariat disruption

### *Significant disruption of Secretariat operations*

	Risk description	Potential causes	Current level	Mitigation strength	Risk appetite	Recent evolution	Long-term outlook
q	<b>Secretariat disruption</b> Significant disruption of Secretariat operations	<ul style="list-style-type: none"> <li>• Catastrophic event</li> <li>• Security threats and kidnapping</li> <li>• Departure of large number of key staff</li> </ul>			<b>BROADLY WITHIN</b>		

A catastrophic event significantly disrupting Secretariat operations could interrupt the Alliance's operations for a prolonged period of time, e.g. due to an inability to maintain communications and coordination internally and externally, an inability to complete disbursements to countries, partners or employees, or an inability to approve, manage, and monitor grants. This could manifest itself through the loss of access to a Gavi workplace facility, the loss of key infrastructure, or the loss of personnel. Potential causes include a natural or man-made disaster, a substantial security threat to staff, or the departure of a large number of key staff. The Secretariat is located in a place with limited exposure to natural disasters and terrorism, however staff are frequently travelling to countries with high security threat levels, and the growing profile of Gavi may attract more anti-vaccine extremists.

The Secretariat has good preventive and detective measures in place, such as building safety and maintenance plans for the facilities; use of uninterruptible power supply; and medical and security risk assessments and travel security measures and monitoring for personnel. To enhance reactive mitigation measures for all areas, the Secretariat is now developing a crisis management framework with emergency response plans and recovery arrangements to ensure crisis management and business continuity after a crisis.

Current risk exposure has decreased significantly following a successful move to the Global Health Campus, and further due to the technology drivers of disruption having been taken out of this risk and included in the separate "IT disruption" risk. Also, following this year's #metoo disclosures and the scandals in the aid sector regarding sexual exploitation, abuse and harassment, Gavi has assessed its exposure to such risks as low being a small Secretariat without country presence. There is a clear code of conduct, a whistle-blower hotline and ombudsman allowing issues to be raised anonymously and addressed, and explicit language on sexual exploitation and abuse has now been included in contracts with counterparts.

The Alliance has a low appetite for risks to Secretariat processes, facilities and people, since these are critical to coordinate the Alliance. The Secretariat seeks to maintain robust processes and management to prevent interruption of business-critical operations. Given the current ongoing mitigation plans, current exposure is broadly within risk appetite.